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SHDKT PROCEEDINGS AND ORDERS DATE: [03/15/95]

CASE NBR: [94100372] CFX STATUS: [GRANTED ]
SHORT TITLE: [Shalala, Sec., H&HS ]
VERSUS [Whitecotton, Margaret, et al] DATE DOCKETED: [082994]
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| 1 | Jul 18 1994 | G | | Application (A94-30) to extend the time to file a petition for a writ of certiorari from July 28, 1994 to August 29, 1994, submitted to The Chief Justice. |
| 2 | Jul 19 1994 | | | Application (A94-30) granted by the Chief Justice extending the time to file until August 27, 1994. |
| 3 | Aug 29 1994 | G | | Petition for writ of certiorari filed. |
| 4 | Sep 30 1994 | | | Brief of respondents Magaaret Whitecotton, et al. in opposition filed. |
| 5 | Oct 5 1994 | | | DISTRIBUTED. October 28, 1994 (Page 1) |
| 6 | Oct 20 1994 | X | | Reply brief of petitioner filed. |
| 7 | Oct 31 1994 | | | Petition GRANTED. |
| | | | | ********** |
| 8 | Dec 15 1994 | | | Joint appendix filed. |
| 10 | Dec 15 1994 | | | Brief of petitioner Donna E. Shalala, Secretary of Health and Human Services filed. |

PREVIOUS 1 1 EXIT

Last page of docket

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| 11 | Dec 15 1994 | | | Brief amicus curiae of American Academy of Pediatrics filed. |
| 12 | Dec 21 1994 | | | SET FOR ARGUMENT TUESDAY, FEBRUARY 28, 1995. (1ST CASE) |
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| 15 | Jan 10 1995 | | | Record filed. |
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| 16 | Jan 17 1995 | X | | Brief of respondents Magaret Whitecotton, et al. filed. |
| 17 | Jan 17 1995 | X | | Brief amici curiae of Dissatisfied Parents Together, et al. filed. |
| 18 | Feb 21 1995 | X | | Reply brief of petitioner filed. |
| 19 | Feb 28 1995 | | | ARGUED. |

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No.



# In the Supreme Court of the United States

OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DREW S. DAYS, III
*Solicitor General*

FRANK W. HUNGER
*Assistant Attorney General*

EDWIN S. KNEEDLER
*Deputy Solicitor General*

IRVING L. GORNSTEIN
*Assistant to the Solicitor General*

BARBARA C. BIDDLE
RICHARD A. OLDERMAN
KAREN P. HEWITT
*Attorneys*

*Department of Justice*
*Washington, D.C. 20530*
*(202) 514-2217*

71 pp

## QUESTIONS PRESENTED

1. Whether, under the National Childhood Vaccine Injury Act, 42 U.S.C. 300aa-11(c), proof that a manifestation of a brain injury occurred shortly after administration of a vaccine creates a presumption that the vaccine caused the "onset" of the injury, when the injury had already manifested itself prior to administration of the vaccine.

2. Whether, if such a presumption of causation is created, the government may rebut it by showing that an identified preexisting condition caused the injury, even though the specific cause of that condition is unknown.

## PARTIES TO THE PROCEEDINGS

The petitioner is Donna E. Shalala, the Secretary of Health and Human Services. The respondents are Margaret, Kay and Michael Whitecotton.

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# In the Supreme Court of the United States

OCTOBER TERM, 1994

No.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

## PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Solicitor General, on behalf of Donna E. Shalala, the Secretary of Health and Human Services, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

### OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-9a) is reported at 17 F.3d 374. The opinion of the United States Claims Court (now the Court of Federal Claims) (App., *infra*, 10a-23a) and the decision of the Special Master (App., *infra*, 24a-43a) are unreported.

### JURISDICTION

The judgment of the court of appeals was entered on February 15, 1994. A petition for rehearing was

denied on April 29, 1994. App., *infra*, 44a-45a. By order dated July 19, 1994, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 27, 1994 (a Saturday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATUTORY PROVISIONS INVOLVED

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992), provides in pertinent part:

§ 300aa-11. Petitions for compensation

* * * * *

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

* * * * *

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Table, * * *



* * * * *

§ 300aa-13(a)(1). Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, * * *

* * * * *

§ 300aa-14(a). Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and

deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program * * *.

(b) Qualifications and aids to interpretation

* * * * *

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. * * *

* * * * *

§ 300aa-33. Definitions

* * * * *

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health.

**STATEMENT**

1. In 1986, Congress enacted the National Childhood Vaccine Injury Act (Vaccine Act). Pub. L. No. 99-660, Tit. III, 100 Stat. 3755, codified as amended at 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992). Part 1 of the Act directs the Secretary of Health and Human Services to establish a National Vaccine Program designed "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1; see 42 U.S.C. 300aa-1 to 300aa-6 (1988 & Supp. IV 1992). Part 2 of the Act, at issue here, establishes a National Vaccine Injury Compensation Program (Compensation



Program), administered by the Secretary, "under which compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 42 U.S.C. 300aa-10 to 300aa-34 (1988 & Supp. IV 1992).

A proceeding under the Compensation Program is initiated by the filing of a petition in the Court of Federal Claims. 42 U.S.C. 300aa-11(a)(1) (Supp. IV 1992). The claimant may establish entitlement to compensation in either of two ways. Under the first method, the claimant must prove by a preponderance of the evidence that he or she sustained (or had significantly aggravated) any illness, disability, injury, or condition that was caused by the administration of a covered vaccine. See 42 U.S.C. 300aa-11(c)(1)(C)(ii). Under the second method, which respondents have pursued, the claimant may rely on the Vaccine Injury Table (Table), which in effect establishes a rebuttable presumption of causation in certain circumstances.

The Vaccine Injury Table identifies vaccines covered by the Act and lists particular injuries, disabilities, illnesses, and conditions after each vaccine. The Table then specifies for each such injury, disability, illness, or condition a "[t]ime period for first symptom or manifestation of onset or of significant aggravation after vaccine administration." See 42 U.S.C. 300aa-14(a) (1988 & Supp. IV 1992) (setting forth the Table). The claimant is entitled to the rebuttable presumption of causation created by the Table if the court finds on the record as a whole that the claimant has shown by a preponderance of the evidence that he or she sustained (or had significantly aggravated) an illness, disability, injury, or condition set forth in the Table, and

that the "first symptom or manifestation of [its] onset or of [its] significant aggravation" occurred within the time period after vaccine administration set forth in the Table. 42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1)(A). The Secretary may rebut that presumption (and defeat the claim for compensation) by showing by a preponderance of the evidence that the illness, disability, injury, or condition "is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. 300aa-13(a)(1)(B). The term "factors unrelated to the administration of the vaccine" does not, however, "include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. 300aa-13(a)(2)(A).

Cases under the Vaccine Act are adjudicated in the first instance by a special master. 42 U.S.C. 300aa-12(d)(3) (Supp. IV 1992). On motion by a party, the Court of Federal Claims will review the special master's decision. That court may either uphold the decision, or "set aside any findings of fact or conclusion of law * * * found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. 300aa-12(e)(2)(B) (Supp. IV 1992). The decision of the Court of Federal Claims is subject to review in the United States Court of Appeals for the Federal Circuit. 42 U.S.C. 300aa-12(f) (Supp. IV 1992).

2. Respondent Margaret (Maggie) Whitecotton was born on April 22, 1975, with a condition known as microcephaly. App., *infra*, 11a, 33a-34a. Microcephaly is most commonly defined as a head size smaller than two standard deviations below the norm for a child of the same age and sex. *Id.* at 32a. Maggie was borderline microcephalic at birth and



clearly microcephalic before she received her third diphtheria-pertussis-tetanus (DPT) vaccination at about four months of age. *Id.* at 32a-34a.

On August 19, 1975, the day after Maggie received her third DPT vaccine, she suffered a series of seizures. App., *infra*, 2a. Maggie was hospitalized, but she was discharged three days later after a neurological examination indicated that her condition was normal. *Id.* at 40a. In discussing the seizures, the discharge summary expressed one treating physician's opinion that "children with microcephaly and some brain damage [are] unusually susceptible to this vaccine." *Id.* at 30a. Maggie had several seizures over the next five years, but has not had any in recent years. *Id.* at 2a. She now has cerebral palsy and hip and joint problems, and she cannot communicate verbally. *Ibid.*

On August 2, 1990, Maggie's parents, who are also respondents herein, applied for compensation under the Vaccine Act. App., *infra*, 2a. They alleged that Maggie had suffered an "encephalopathy" as a result of her third DPT vaccination. *Ibid.* An encephalopathy is defined by the Vaccine Act as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A). To trigger the presumption of causation under the Table, a symptom or manifestation of the onset or significant aggravation of an encephalopathy must occur within three days after administration of the DPT vaccine. 42 U.S.C. 300aa-14(a) (1988 & Supp. IV 1992). Maggie's parents alleged that her post-vaccine seizures were such a manifestation.

3. The special master denied compensation. App. *infra*, 24a-43a. The special master was persuaded by the evidence concerning Maggie's head size since birth and the testimony of neurologists that "Maggie had suffered an encephalopathy sometime prior to the administration of the DPT vaccine on August 18, 1975." *Id.* at 33a; see also *id.* at 34a ("Whether the injury occurred prior to birth or thereafter, the preponderance of the evidence indicates that Maggie was already encephalopathic prior to August 18, 1975."). The special master therefore concluded that "[h]er original encephalopathy was not a Table injury which followed the August 18 DPT shot." *Id.* at 34a.

The special master also concluded that the seizures that had occurred within the three-day statutory period after administration of the vaccine did not significantly aggravate Maggie's preexisting encephalopathy. App., *infra*, 42a-43a. The special master found that the DPT vaccine "may have caused a temporary encephalopathy evidenced by transient seizure activity, but the seizures did not continue and there was no dramatic turn for the worse in her condition indicating a permanent aggravation of her brain disorder." *Id.* at 42a. Rather, the special master explained, as Maggie "matured neurologically, the complications of whatever caused her microcephaly gradually manifested themselves, just as they do in a typical case involving congenital brain damage." *Ibid.* Accordingly, the special master found "no basis for implicating the vaccine as the cause of any aspect of her present condition." *Id.* at 42a-43a.[1]

[1] The conclusions discussed in the text were also embodied in the special master's formal findings of fact, which recited that Maggie was "born * * * with a brain disorder evidenced by microcephaly which became more pronounced by the age of four months"; that she "suffered transient seizure activity within three days following the administration of the DPT vaccine, the residual effects or complications of which did not continue for six months"; that she "did not suffer a permanent encephalopathy within three days following the said administration of DPT vaccine"; and that "[n]o significant aggravation of Maggie's underlying brain disorder was manifested within three days following the said administration of the DPT vaccine." App. *infra*, 43a.



4. The United States Claims Court (now the Court of Federal Claims) overruled respondents' objections to the special master's decision and entered judgment for the Secretary. App., *infra*, 10a-23a. The court concluded that there was sufficient evidence to support the special master's finding that Maggie was microcephalic before she received her third DPT vaccination, and that her preexisting injury therefore precluded the vaccine from being the cause of the encephalopathy. *Id.* at 19a-21a. The court also concluded that there was sufficient evidence to support the special master's finding that the seizures that occurred within the three-day statutory period after administration of the vaccine were not an indication that the preexisting encephalopathy was significantly aggravated by the vaccine. *Id.* at 23a. As the court viewed the record, "[t]here is simply no evidence that these transient seizures were a sign of permanent brain damage." *Ibid.* Instead, it observed, the evidence indicated "that Maggie's entire clinical history is typical for a person with a condition similar to Maggie's who did not have vaccine complications." *Ibid.*

5. The court of appeals reversed the judgment of the Claims Court and remanded for an award of

compensation. App., *infra*, 1a-9a. The court of appeals held that respondents' showing that Maggie had suffered seizures within three days of administration of the vaccine was sufficient to establish a presumption that the vaccine had caused the encephalopathy. *Id.* at 5a-7a. The court reasoned that "the Table language is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur." *Id.* at 5a.

The court of appeals then held that the Secretary could not rely on Maggie's preexisting microcephaly to show that her injury was caused by a "factor unrelated" to the vaccine. App., *infra*, 7a-8a. The court did not disturb the special master's findings that Maggie "was microcephalic before she received the suspect vaccine," and that her "microcephaly marked [her] as a child likely to experience developmental problems." *Id.* at 8a. Moreover, the court acknowledged that "[l]ogically, these findings point to some preexisting condition, and not the vaccine, as the source of Maggie's injury." *Ibid.* Nonetheless, the court held that Maggie's microcephaly was not a "factor unrelated" to the administration of the vaccine within the meaning of the Vaccine Act. *Id.* at 6a. Relying on its decision in *Koston* v. *Secretary, Dep't of Health & Human Servs.*, 974 F.2d 157, 160-161 (1992), the court concluded that Maggie's microcephaly was an "idiopathic" factor because, although it was preexisting, its specific cause could not be identified. App., *infra*, 7a-8a.[2]

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[2] The Secretary's petition for rehearing, with suggestion of rehearing en banc, was denied, with one judge dissenting. App., *infra*, 44a-45a.



## REASONS FOR GRANTING THE PETITION

The court of appeals has interpreted the National Childhood Vaccine Injury Act of 1986 to require compensation in circumstances in which logic compels the conclusion that a child's condition was not caused by a vaccine. That interpretation is demonstrably at odds with the text of the Act and threatens the fiscal integrity of the compensation program. Because the Federal Circuit is the only court of appeals with authority to review Vaccine Act cases, review by this Court is necessary to correct that circuit's serious misreading of the Act and to restore the integrity of the National Vaccine Injury Compensation Program.

1. The court of appeals has held that there is a statutory presumption that a vaccine caused the onset of an injury or condition if a manifestation of the injury or condition happens to occur within a specified time after administration of the vaccine, even though that injury or condition already had manifested itself prior to administration of the vaccine. An example is useful in illustrating just how extraordinary that holding is. If a child had experienced seizures regularly from birth, a showing that the child happened to experience an identical seizure within the statutory period after administration of the vaccine would create a presumption that the vaccine had caused the onset of a brain impairment. If the court of appeals is correct, Congress has mandated a presumption of causation in circumstances in which the only available indications are that the vaccine did *not* cause the injury or condition.

A presumption of that kind would make no sense, but its adverse consequences for the integrity of the Compensation Program might be mitigated if the

Secretary could rebut the presumption by showing that the child's current injury or disability was caused by a preexisting condition. The court of appeals has further held, however, that the Secretary cannot rebut the presumption by tying the injury or disability to a preexisting condition, unless the Secretary can also identify the specific cause of that preexisting condition—something the Secretary will be unable to do in many cases. For example, even if the Secretary could prove that the child had only a partial brain at birth and that such a condition invariably results in the kind of injury or disability from which the child suffers, the presumption would not be rebutted unless the Secretary were able to identify what had caused the child to have a partial brain. Thus, under the court of appeals' decision, compensation is now required in Vaccine Act cases in circumstances in which the evidence logically compels the conclusion that a known preexisting condition, and not the vaccine, caused the child's current injury or disability.

The court understood that its decision would have that effect. The court expressly acknowledged that because Maggie was microcephalic before administration of the vaccine—and that because Maggie's microcephaly marked her as someone likely to experience developmental problems—it was logical to conclude that a preexisting condition and not the vaccine had caused her injury. App., *infra*, 8a. The court concluded, however, that Congress had mandated compensation anyway. *Id.* at 9a.

2. a. The illogical conclusion reached by the court of appeals is demonstrably at odds with the text of the Vaccine Act. Under 42 U.S.C. 300aa-11(c)(1)(C)(i), a presumption of causation exists when a



claimant shows by a preponderance of the evidence that he or she—

> sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a specified] vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.

See 42 U.S.C. 300aa-13(a)(1)(A). That statutory language creates a presumption in two kinds of cases: those in which the claimant shows that he or she first began to suffer from an injury or condition after administration of the vaccine ("onset" cases), and those in which the claimant shows that he or she suffered from a Table injury or condition before receiving the vaccine, but that it markedly worsened after that time ("significant aggravation" cases). In this case, the "first" manifestation of the "onset" of Maggie's brain injury or condition was her preexisting microcephaly. The plain language of the Act therefore makes clear that respondents could not benefit from a statutory presumption of causation absent proof that a manifestation of a "significant aggravation" of Maggie's preexisting brain injury or condition occurred in the statutory three-day period—a showing that respondents failed to make.

The court of appeals was of the view that the statutory phrase "first symptom or manifestation of the onset" means that a claimant is entitled to a presumption of causation as long as *any* symptom or manifestation of an underlying injury or condition occurred within the statutory period. App., *infra*, 5a-

7a. That interpretation cannot be reconciled with the plain meaning of the statutory text and therefore must be rejected. *Connecticut Nat'l Bank* v. *Germain*, 112 S. Ct. 1146, 1149 (1992). The term "first" means "before all others," and the term "onset" means "a beginning or start." *The Random House Dictionary of the English Language* 723, 1354 (1987). When an injury or condition has manifested itself prior to administration of the vaccine, a manifestation after administration cannot be the "first." And when an injury or condition had its start before administration of the vaccine, any manifestation that occurs after that time cannot be a manifestation of the "onset" of the injury or condition. Simply put, the phrase "first symptom or manifestation of the onset" does not mean merely a *further* symptom or manifestation of a *preexisting* injury.

The court of appeals' interpretation is also flawed because it fails to give any meaning to the statutory text creating a presumption of causation when a preexisting condition was significantly aggravated after the administration of a vaccine. See *United States* v. *Nordic Village, Inc.*, 112 S. Ct. 1011, 1015 (1992) ("the settled rule [is] that a statute must, if possible, be construed in such fashion that every word has some operative effect"). If, as the court of appeals concluded, a presumption of causation arises whenever any symptom occurs within the statutory period, there would never be a need for a claimant to establish a significant aggravation of a preexisting injury. The "significant aggravation" presumption makes sense only if a finding of a pre-vaccine condition precludes the claimant from establishing a post-vaccine "onset." Thus, the necessary implication of the "significant aggravation" presumption is that there can-



not be a presumption of causation when a condition that manifested itself before administration of the vaccine did not get markedly worse afterwards. See 42 U.S.C. 300aa-33(4) (defining "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health").

The legislative history of the Vaccine Act confirms that obvious point. The House Report explains that the Act does not "include compensation for conditions which might legitimately be described as pre-existing (*e.g.*, a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (*e.g.* a child with monthly seizures who, after vaccination, has seizures on a daily basis)." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 14-16 (1986).

b. The court of appeals purported to find support for its interpretation of the statutory presumption in two other provisions of the Act. The court, however, misperceived the effect of each.

First, the court of appeals deemed it significant that Congress provided that a residual seizure disorder could be found if the claimant "did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved." 42 U.S.C. 300aa-14(b)(2). Because Congress included no such limitation with respect to an encephalopathy, the court reasoned, it must not have intended to require claimants to show that there was no preexisting symptom or manifestation of that injury or condition. App., *infra*, 5a-6a. The special

provision addressing seizure disorders was necessary, however, because seizures accompanied by high fevers may not be symptomatic of a seizure disorder. To avoid any uncertainty about whether the existence of pre-vaccine seizures accompanied by high fevers would preclude a showing of post-vaccine onset, Congress made clear that they would not. Thus, the provision does not indicate that Congress required claimants to show the absence of preexisting symptoms in residual seizure disorder cases, but not in others. Instead, it clarifies how the general statutory requirement—that a claimant must show that a manifestation that occurred within the statutory period was the first such manifestation—should be applied in the special circumstances of alleged residual seizure disorders.

The court of appeals also attributed significance to the provision in the Act that permits a prima facie case to be defeated upon proof that "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances" caused the child's injury or condition. 42 U.S.C. 300aa-13(a)(2)(B). According to the court, "[i]t would make no sense to allow proof by the Secretary of birth trauma as a factor unrelated if the petitioner were required to prove that no such preexisting injury occurred as an element of the Table case." App., *infra*, 6a. The "factors unrelated" provision, however, serves the distinct purpose of permitting the Secretary to rebut a prima facie case of causation by showing that, even though there was no preexisting symptom or manifestation of the injury or condition, it nonetheless was caused by a preexisting factor, such as birth trauma. That provision is therefore entirely compatible with the requirement that the claimant must



show that a post-vaccine manifestation of an injury was the "first" such manifestation in order to establish a presumption of post-vaccine "onset."

3. The court of appeals' further holding that the Secretary could not rely on Maggie's preexisting microcephaly to rebut a prima facie case of causation likewise rests on a serious error of statutory interpretation. The Act precludes the Secretary from relying on an "idiopathic" factor to rebut a prima facie case, and medical dictionaries uniformly define "idiopathic" as "of unknown cause." *International Dictionary of Medicine and Biology* 1398 (1986); *Stedman's Medical Dictionary* 762 (25th ed. 1990); *Dorland's Illustrated Medical Dictionary* 815 (27th ed. 1988); *American Medical Association Encyclopedia of Medicine* 566 (1989). The Secretary therefore cannot attempt to defeat a prima facie case by relying on a statement from an expert such as "I have no idea what caused the injury, but it could not have been the vaccine." That statutory protection for the claimant is important. There is a considerable body of medical opinion that serious adverse neurological events following vaccinations are exceedingly rare. Because the Act precludes reliance on "idiopathic" or "unknown" factors to rebut a prima facie case, the Secretary could not rely on that body of medical opinion alone to rebut a prima facie case. The Secretary instead must point to some identifiable condition as an explanation for a claimant's injuries. When the Secretary is unable to do that, the Act requires that the claimant receive the benefit of the doubt on the issue of causation, even though it may be unlikely that the vaccine actually caused the injury.

Here, however, the Secretary *did* identify a specific preexisting condition—microcephaly—to explain respondent's brain injury. That condition predictably leads to retardation, and Maggie had that condition from birth. As the court of appeals recognized, that evidence logically pointed to a preexisting condition, rather than the vaccine, as the cause of her brain injury. App., *infra*, 8a.

The court of appeals nevertheless concluded that the Secretary was relying on an "idiopathic" factor because the Secretary could not in turn identify the cause of Maggie's preexisting microcephaly. App., *infra*, 7a-8a. The court of appeals took the requirement that an unrelated factor must be non-idiopathic one step further back than Congress intended. The Act gives the claimant the benefit of the doubt in cases in which the Secretary cannot point to any identified condition that justifies elimination of the vaccine as the cause of the injury. It does not require compensation in circumstances in which the Secretary can point to a specific condition that logically eliminates the vaccine as the cause of the child's current injury or disability, simply because the cause of that specific condition is unknown.

The legislative history supports that reading of the statutory text. The House Report states that unrelated factors cannot include "speculative or hypothetical matters or explanations." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 18 (1986). It makes clear, however, that the Secretary may rebut the presumption of causation by relying on "other, defined illnesses or factors." *Ibid.* The court of appeals' contrary view makes no sense. Congress could not have intended to permit compensation in circumstances in which the evidence clearly shows that a



preexisting condition, and not the vaccine, caused the child's injury or disability.

4. The court of appeals' decision will affect hundreds of pending and future Vaccine Act cases. The average cost of compensating a child with severe brain injuries is approximately $1 million. The court of appeals' decision will therefore have an enormous financial impact on the compensation program.

Most immediately, the decision threatens the fiscal integrity of the program for funding retrospective cases, *i.e.*, those cases based on vaccines administered before October 1, 1988. See 42 U.S.C. 300aa-15(j) (1988 & Supp. IV 1992) and 300aa-16(a)(1) (1988 & Supp. IV 1992). In the past, the annual appropriation for retrospective cases (now funded at $110 million per year[3]) has been routinely exhausted. After reviewing the medical records in cases that are likely to be resolved in the next two years, the Secretary has estimated that if allowed to stand, the legal standards established in this case will result in more than $20 million per year in additional compensation being awarded in retrospective cases alone. Such awards could lead to a chronic underfunding of that program. An unfortunate consequence would be that persons who deserve compensation under the Act would have to stand in line behind those who do not.

Moreover, the decision's impact is not limited to retrospective cases. The Secretary expects between 100 and 200 new Vaccine Act cases to be filed each year for the foreseeable future. With the addition of new covered vaccines (see 42 U.S.C. 300aa-14(c)), the number of cases could climb even higher. The

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[3] See 42 U.S.C. 300aa-15(j) (Supp. IV 1992), as amended by Pub. L. No. 103-66, Tit. XIII, § 13632(b), 107 Stat. 646.

court of appeals' decision therefore could readily require in excess of $200 million in additional compensation over the next ten years.

The decision is already affecting the adjudication of Vaccine Act cases. For example, in *Cepeda* v. *Secretary of the Dep't of Health and Human Servs.*, No. 90-2664V (Fed. Cl. July 12, 1994), the special master granted compensation in a case in which the Secretary had claimed that post-vaccine symptoms were caused by a preexisting neurological disorder. The special master concluded that the decision in this case had caused a "dramatic change" in the law governing Vaccine Act cases. Slip op. 2. She specifically noted that the court's decision meant that onset claims and significant aggravation claims "are now identical," and that significant aggravation "need no longer be referenced in the resolution of any Table cases." *Id.* at 5. The special master also observed that the court's decision had altered the previous understanding that the presumption of causation could be rebutted "without the need to establish a particular etiology for a preexisting condition." *Ibid.* The special master viewed the decision in this case as creating a "conundrum," because it requires compensation even when "there is no possible sense in which a condition can be attributed to the vaccine." *Ibid.*; see also *Skinner* v. *Secretary of Health & Human Servs.*, No. 90-1051V (Fed. Cl. May 31, 1994) (compensation awarded in light of *Whitecotton*).

The Federal Circuit has exclusive jurisdiction over appeals in Vaccine Act cases. Thus, unless reviewed by this Court, the Federal Circuit's decision in this case will be the last word on the issues presented here. Because the decision badly misreads the Vaccine Act and will have a serious adverse impact on the integrity and financing of the Compensation Program, review by this Court is warranted.



## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

DREW S. DAYS, III
*Solicitor General*

FRANK W. HUNGER
*Assistant Attorney General*

EDWIN S. KNEEDLER
*Deputy Solicitor General*

IRVING L. GORNSTEIN
*Assistant to the Solicitor General*

BARBARA C. BIDDLE
RICHARD A. OLDERMAN
KAREN P. HEWITT
*Attorneys*

AUGUST 1994

**APPENDIX A**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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92-5083, 93-5101

MARGARET WHITECOTTON, by her
next friends, KAY WHITECOTTON and
MICHAEL WHITECOTTON, PETITIONERS-APPELLANTS

*v.*

SECRETARY OF DEPARTMENT OF HEALTH AND
HUMAN SERVICES, RESPONDENT-APPELLEE

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Decided: February 15, 1994

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Before: NEWMAN, MAYER, and CLEVENGER, Circuit Judges.

MAYER, Circuit Judge.

Kay and Michael Whitecotton appeal the judgment of the United States Court of Federal Claims,[1] No. 90-692V (Jan. 14, 1992), upholding the special master's denial of their petition under the National Childhood Vaccine Injury Act of 1986. The Whitecottons also appeal the January 7, 1993, order of the Court

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[1] The United States Claims Court was renamed the Court of Federal Claims on October 29, 1992, during the course of proceedings in this case before that court. Federal Courts Administration Act of 1992, Pub. L. No. 102-572, § 902(a), 106 Stat. 4506, 4516. For clarity, we use the court's present name.

of Federal Claims denying their motion for relief based on newly discovered evidence. We reverse and remand.

*Background*

Margaret Whitecotton (Maggie) was born without complications on April 22, 1975. Maggie was a small child—her head circumference at birth was 12.5 inches, or 32 centimeters, placing her in the second percentile on a standard growth chart. Although she might be considered microcephalic based on this measurement, Maggie was healthy, developmentally and physically, until she received her third diphtheria-pertussis-tetanus (DPT) vaccination on August 18, 1975. Maggie's mother took her to the emergency room that evening, after she allegedly saw the child suffer a series of seizures. The treating physician saw no evidence of seizures and discharged Maggie that same night. The next day, Maggie's mother took her to see the family doctor. That doctor saw Maggie experience a series of clonic seizures.

Although Maggie suffered occasional seizures over the next five years, she has suffered none in recent years. She is, however, mentally and physically disabled. She has cerebral palsy, has hip and joint problems, and cannot communicate verbally.

On August 2, 1990, Maggie's parents, as her legal representatives, applied for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 to 300aa-34 (1988 & Supp. III 1991). They asserted that Maggie suffered a compensable encephalopathy as a result of the August 18 vaccination. The Secretary of Health and Human Services responded that Maggie's condition arose instead from a chronic organic brain syndrome that



preexisted the vaccination, and that, therefore, she deserved no compensation under the Act.

On August 16, 1991, the special master denied compensation, finding that Maggie was born with a brain disorder that was responsible for her present disabilities. The Whitecottons sought review of the decision in the Court of Federal Claims, which affirmed the decision of the special master.

On March 27, 1992, the Whitecottons filed an appeal in this court, which stayed the proceedings pending resolution in the Court of Federal Claims of the Whitecottons' motion for relief from judgment under Rule 60(b)(2). When that motion was denied, the Whitecottons sought review of that denial in this court as well. We now consider the Whitecottons' consolidated appeals.

*Discussion*

I.

The Whitecottons challenge the interpretation of the Vaccine Act adopted by the special master and affirmed by the Court of Federal Claims, which they argue robbed them of the statutory presumption of causation created by Congress to facilitate recovery for likely vaccine injuries. We review such legal questions de novo. *Hodges v. Secretary, Dep't of Health and Human Services*, 9 F.3d 958, 960 (Fed. Cir. 1993).

The asserted presumption, designed to excuse petitioners from the often onerous burden of proving causation in vaccine cases, attaches whenever the petitioners meet the requirements of the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a). Specifically, petitioners must demonstrate that the injured child re-

ceived a vaccine enumerated in the Table, that the child sustained one of the injuries set forth in the Table within the statutory time period after vaccination, and that the effects of the injured lasted for more than six months, resulting in more than $1,000 of expenses. *Id.* § 300aa-11(c). If the petitioners fail to meet the Table requirements, they can recover compensation only on the more difficult showing of actual causation. *Id.* § 300aa-11(c)(1)(C)(ii). Once petitioners satisfy their burden of proving presumptive or actual causation by a preponderance of evidence, they are entitled to recover unless the Secretary shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine. *Id.* § 300aa-13(a)(1)(B).

Here, the parties do not dispute that Maggie suffered an encephalopathy that led to her present retardation and cerebral palsy. The only questions are when the encephalopathy occurred and the effect of the date of onset on recovery under the Act.

## II.

The Whitecottons say both the special master and the Court of Federal Claims misinterpreted the law, allowing the Secretary to defeat their proven Table injury with a showing of a preexisting brain disorder evidenced by microcephaly, an idiopathic factor unrelated to the vaccine. The Secretary responds that the special master never reached the "factor unrelated" question because the Whitecottons failed to establish their prima facie case when they could not prove that Maggie's August 19, 1975, seizures were the first manifestation of the encephalopathy.

While the special master did conclude that Maggie suffered no Table encephalopathy, we do not agree.



Nowhere does the statute expressly state that proof of a Table encephalopathy includes a showing that the child sustained no injury prior to administration of the vaccine. The Act requires that a petition for compensation include affidavits demonstrating that the first manifestation of the injury occurred within Table time after vaccination, 42 U.S.C. § 300aa-11(c)(1)(C)(i), but the Table itself provides that the statutory period is a "[t]ime period for first symptom or manifestation of onset . . . after vaccine administration." *Id.* § 300aa-14(a). The distinction is significant: the Table language is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur.

Congress could have expressly made the absence of preexisting injury an element of the prima facie case had it so intended. In fact, the qualifications and aids to interpretation of the Table do that for one type of injury, providing that "[a] petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion . . . before the first seizure or convulsion after the administration of the vaccine . . . ." *Id.* § 300aa-14(b)(2). Subsequent subsections dealing with encephalopathy place no such limitation on finding Table injury. *See id.* § 300aa-14(b)(3)(A)-(B).[2]

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[2] Indeed, the Vaccine Act here provides explicitly that

> [i]f . . . it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma or metabolic disturbances the encephalopathy *shall not be* considered to be a condition set forth in the table. . . .

42 U.S.C. § 300ee-14(b)(3)(B) (emphasis added). This provision prevents a petitioner from establishing her Table case

Since Congress expressly restricted residual seizure disorders to instances where no seizure occurred before vaccine administration, we assume its failure similarly to limit encephalopathy was intentional. *See Russello v. United States*, 464 U.S. 16, 24 (1983) ("Had Congress intended to restrict § 1963(a)(1) to an interest in an enterprise, it presumably would have done so expressly as it did in the immediately following subsection (a)(2)"); *The Ad Hoc Committee v. United States*, —— F.3d —— No. 93-1239, slip op. at 6 (Fed. Cir. January 5, 1994).

Moreover, the Act provides that the "factors unrelated" that can defeat a prima facie case may include "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances . . . ." 42 U.S.C. § 300aa-13(a)(2)(B). This section manifestly contemplates that birth trauma, an injury that necessarily must precede administration of any vaccine, can qualify as a factor unrelated to the vaccine and bar recovery. It would make no sense to allow proof by the Secretary of birth trauma as a factor unrelated if the petitioner were required to prove that no such preexisting injury occurred as an element of the Table case.

Because the statute makes sense only if the Secretary bears the burden of proving a preexisting encephalopathy, we decline the Secretary's argument that the Whitecottons failed to prove their prima facie case. It is undisputed that Maggie suffered an encephalopathy. It is also undisputed that Maggie's encephalopathy manifested itself in the form of seiz-

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if preponderant evidence of record shows that the encephalopathy resulted from one of the four statutorily enumerated causes. The Secretary does not argue that Maggie's encephalopathy arose from one of these causes.



ures occurring within Table time after vaccination. This suffices to show a Table injury. The Whitecottons deserve the benefit of the Act's presumed causation.

III.

The special master based his denial of the petition on the evidence of Maggie's microcephaly. The Secretary offered evidence that microcephalic children are likely to experience developmental difficulties because head growth follows brain development. The special master agreed, reasoning that Maggie's disabilities arose from a preexisting brain disorder, which might bar recovery as a factor unrelated to the DPT vaccine. However, just as the Act defines what can be a "factor unrelated," it states what cannot: a factor unrelated to the administration of the vaccine "does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. § 300aa-13(a)(2)(A). The Act does not limit its prohibition of idiopathic, or unknown, causes to those demonstrably arising after administration of the suspect vacine; it forbids the use of any such cause to defeat a petition.

We addressed this same provision in *Koston v. Secretary, Dep't of Health and Human Services*, 974 F.2d 157, 160-61 (Fed. Cir. 1992), and rejected the notion that a preexisting idiopathic condition can support a finding of alternate causation. In *Koston*, the Secretary first conceded causation of the child's residual seizure disorder. An independent medical examination revealed that the child suffered from Rett Syndrome, a condition manifested by mental regression and peculiar behavioral symptoms. The Secretary then sought to withdraw the concession of

causation, arguing that because Rett Syndrome was thought to arise from prenatal factors the vaccine could not have been responsible for the child's condition.

We did not accept the Secretary's position because while the medical community believed Rett Syndrome to be genetically determined or derived from a metabolic defect, medical science had not yet firmly identified its cause. Rett Syndrome being an idiopathic condition, an illness with no known cause, it could not support a finding of alternate causation. *Id.* at 161.

We are faced with a similar situation here. The special master found that Maggie was microcephalic before she received the suspect vaccine. He also found that her microcephaly marked Maggie as a child likely to experience developmental problems. Logically, these findings point to some preexisting condition, and not the vacine, as the source of Maggie's injury. However, the record does not identify this condition. The Secretary's expert testified that microcephaly is often idiopathic, and could point to no specific cause for Maggie's microcephaly. He could only speculate that Maggie suffered a brain injury at some time before she received the vaccine in August 1975. The special master adopted this speculation, stating that as Maggie matured, "the complications of *whatever caused her microcephaly* gradually manifested themselves," and concluded that "there is no basis for implicating the vaccine as the cause of any aspect of her present condition." *Whitecotton v. Secretary, Dep't of Health and Human Services*, No. 90-692V, slip op. at 13 (Cl. Ct. Spec. Mstr. Aug. 16, 1991) (emphasis added). This ignores the statutory presumption.



Congress intended that vaccine awards be made "quickly, easily, and with certainty and generosity." H.R. Rep. No. 908, 99th Cong. 2d Sess. 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6344. This purpose would not be served by allowing the Secretary to avoid an award by offering "speculative or hypothetical matters or explanations" of alternate causation; under the Act, a Table injury must be presumed vaccine-related unless demonstrated to arise from "other, defined illnesses or factors." *Id.* at 18, 1986 U.S.C.C.A.N. at 6359. This may result in " 'compensation to some children whose illness is not, in fact, vaccine related,' " *Koston*, 974 F.2d at 161 (citations omitted), but that is what Congress intended. As in *Koston*, "we have an unknown cause and [symptoms] occurring within three days, the period the Vaccine Injury Table sets for recovery. That is the end of our inquiry . . . ." *Id.* The Whitecottons established their prima facie case, and so get the benefit of presumptive causation.

*Conclusion*

Accordingly, the judgment of the Court of Federal Claims is reversed and the case is remanded to determine compensation.

COSTS

Costs to Kay and Michael Whitecotton.

*REVERSED AND REMANDED*

APPENDIX B

IN THE UNITED STATES CLAIMS COURT

No. 90-692-V

MARGARET WHITECOTTON, by her next friends, KAY WHITECOTTON and MICHAEL WHITECOTTON, PETITIONER

*versus*

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENT

[Filed Jan. 14, 1992]

OPINION and ORDER

TURNER, Judge.

Petitioner seeks review of the special master's August 16, 1991 decision denying compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 - 300aa-34 (1988), *as amended* by several public laws codified in 42 U.S.C.A. §§ 300aa-10 - 300aa-34 (West Supp. 1991) (Vaccine Act), for injuries allegedly suffered as a result of a diphtheria-pertussis-tetanus (DPT) vaccination. For the reasons given below, we conclude that the special master's decision was not arbitrary or otherwise unlawful, and the decision will be sustained.



I

Margaret (Maggie) Whitecotton was born on April 22, 1975. She was delivered without complications. Maggie received her third DPT vaccination on August 18, 1975. According to her mother, Maggie began to experience seizures (jerking of the arms and eye blinking) later that evening. Her mother took her to an emergency room that night, but the treating physician did not observe any seizure activity. On August 19, 1975, Maggie's mother took Maggie to their family practitioner's office. While Maggie was there, the physician saw her experience a series of clonic seizures. Maggie was hospitalized for the next three days.

At birth, Maggie's head circumference was 12.5 inches. This figures placed her head size in the second percentile on the standard growth chart,[1] where she remained during the first three months of her life. On August 20, 1975, Maggie's head circumference was below the second percentile, and in the months that followed her head size continued to fall further from the normal range.

In February 1976, Maggie's parents hospitalized her for ten days with a possible seizure disorder after she became still, flaccid and pale. She had no seizures while in the hospital, and an EEG taken on the day

[1] The significance of noting that Maggie's head size at birth was in the second percentile is to indicate that statistically 98% of females had larger head circumferences at birth.

after admission was normal. The treating personnel concluded that her upper airway was obstructed by mucus. In January 1977, Maggie developed a fever of about 104 degrees in connection with an upper respiratory infection and was diagnosed with a febrile convulsion. On August 28, 1979, Maggie went limp and her eyes rolled. Her mother took her to an emergency room where she threw up mucus. The hospital admitted her for observation, but she did not have any further problems. Her doctor gave her medication for pneumonitis because a chest x-ray suggested pneumonia in the left lung. It was thought that her initial problem had probably been choking secondary to mucus in her throat. On March 21, 1980, the day after reeciving a DT (diphtheria and tetanus) shot, Maggie had a grand mal seizure. Her temperature was recorded at 102 degrees. Maggie has not had any seizures in recent years.

Currently, Maggie has cerebral palsy and mental retardation; she has required surgery for hip and joint problems. She is unable to communicate verbally.

Petitioner claims that she suffered an encephalopathy and a residual seizure disorder, which are both injuries listed in the Vaccine Injury Table, as a result of the August 18, 1975 vaccination. Respondent contends that Maggie's condition is a result of a factor unrelated to the administration of the vaccine. Specifically, respondent claims that Maggie suffered from a preexisting condition called chronic organic brain syndrome. The special master conducted an evidentiary hearing on June 4, 1991 to determine whether petitioner was entitled to compensation



under the Vaccine Act. The special master denied compensation to petitioner for both injuries on August 16, 1991. Petitioner filed a motion for review contending that findings made by the special master were arbitrary, capricious or otherwise unlawful.

II

Section 300aa-11(c)(1) of title 42, U.S.C., lists the matters which a petitioner seeking compensation for a vaccine-related injury must prove. According to section 300aa-11(c)(1), petitioner must prove (1) that the vaccine she received was listed in the Vaccine Injury Table; (2) jurisdictional requirements; (3) that she sustained an injury or had significantly aggravated a preexisting injury; (4) actual or presumed causation; (5) that the residual effects of the injury lasted for more than six months after the administration of the vaccine, resulting in more than $1,000 in unreimbursable expenses; and (6) that there has been no recovery in a previous civil suit. If each of these requirements is established by a preponderance of the evidence, then the burden shifts to the government to prove by a preponderance of the evidence that the injury was caused by some factor unrelated to the administration of the vaccine. 42 U.S.C.A. § 300aa-13(a)(1).

As section 300aa-11(c)(1)(C) of title 42 indicates, causation may be established in two ways. When an injury listed in the Vaccine Injury Table begins to manifest itself within the time period set forth in the Table for the vaccine in question, then causation is presumed. 42 U.S.C.A. § 300aa-11(c)(1)(C)(i). Alternatively, injuries which are not listed in the Vaccine Injury Table or which do not manifest themselves within the time specified in the

Table may be established by proof of actual causation. 42 U.S.C.A. § 300aa-11(c)(1)(C)(ii). Petitioner pursued this case under the first method.

## III

At the June 4, 1990 evidentiary hearing, two expert witnesses, Dr. Ellen Kitts and Dr. Gerald Slater, testified for petitioner. Another expert witness, Dr. Owen Evans, testified for respondent.

Dr. Kitts, a physician specializing in pediatric physical medicine and rehabilitation, testified that her opinion, based upon a reasonable degree of medical certainty, was that Maggie was not born with neurological damage nor did she have brain damage prior to August 18, 1985. Dr. Kitts testified that the DPT vaccination was the sole cause of Maggie's cerebral palsy and mental retardation.

Dr. Slater, a pediatrician and pediatric neurologist, testified that his opinion, based upon a reasonable degree of medical certainty, was that Maggie suffered an injury or an aggravation of an injury as a result of the DPT shot. Nonetheless, Dr. Slater acknowledged the possibility that Maggie was microcephalic prior to the vaccination. He testified that there was no uniformly accepted precise definition of microcephaly (abnormally small head size) but that it was generally thought to be either two or three standard deviations below the mean on the standard growth chart.[2] Dr. Slater also testified that the seizures occurring after the vaccination were transient and that the subsequent seizure-like occurrences were questionable.

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[2] A standard deviation is a measure of the extent to which the population is disbursed on either side of the mean.



Dr. Evans, a pediatric neurologist, testified that Maggie had congenital organic brain syndrome that was characterized by microcephaly, mental retardation and cerebral palsy. Dr. Evans testified that the definition of microcephaly differed among physicians but that he considered it to be at or below the second percentile on the standard growth chart. Because Maggie was in the second percentile at birth, he considered her to be born with a brain disorder manifested by microcephaly. Dr. Evans testified that his opinion, based upon a reasonable degree of medical certainty, was that the seizures Maggie suffered on August 19, 1975 were related to her congenital organic brain syndrome, not her DPT vaccination.

After hearing the testimony of these experts along with the testimony of Maggie's mother, and considering the clinical history of Maggie, Special Master Baird denied compensation for a residual seizure disorder and an encephalopathy. The special master denied compensation for the residual seizure disorder on the grounds that petitioner did not establish that she suffered from a residual seizure disorder within the meaning of the Vaccine Act or that the residual effects lasted for more than six months following the administration of the vaccine. The special master denied compensation for the encephalopathy on the ground that Maggie had a preexisting brain disorder manifested by microcephaly which accounted for her condition. Moreover, the special master concluded that her preexisting brain disorder was not significantly aggravated by the vaccine.

## IV

Section 300aa-12(e)(2) of title 42 provides that upon the filing of a motion for review, the United States Claims Court may review the record and:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The Federal Circuit has held that the "arbitrary and capricious" standard in subparagraph (B) is to be "highly deferential" to the special master and that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Secretary of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

V

The special master found that petitioner was not entitled to compensation for a residual seizure disorder because she did not prove two of the elements listed in section 300aa-11(c)(1) by a preponderance of the evidence. Specifically, the special master found that petitioner failed to establish that she suffered from a residual seizure disorder within the meaning of the Vaccine Injury Table or that the residual effects lasted for more than six months following the administration of the vaccination.



Although the special master determined that Maggie had a series of afebrile clonic seizures on August 19, 1975, he concluded that Maggie did not sustain a residual seizure disorder within the meaning of the Vaccine Act. Petitioner contends that the special master unlawfully required her to prove that she had an additional seizure sometime outside of the six month period following the vaccination. The provision setting forth "[q]ualifications and aids to interpretation" states that:

> A petitioner *may* be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—
>
> . . . .
>
> (B) in the case of [the DPT vaccine], the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

42 U.S.C.A. § 300aa-14(b)(2) (emphasis added). Plainly, the provision does not require a finding of a residual seizure disorder if its conditions are met. Both the title, "[q]ualifications and aids to interpretation," and the use of the word "may" rather than "shall" in the first sentence suggest that section 14(b)(2) does not compel a finding of a residual seizure disorder if its conditions are met. Thus, the

fact that Maggie's seizures on August 19, 1975 may have been sufficient to support a finding of a residual seizure disorder does not render unlawful the special master's decision to find otherwise.

Moreover, the special master's decision cannot be considered to be arbitrary or capricious. Petitioner's own expert, Dr. Slater, testified that Maggie's seizures on August 19, 1975 were "transient in that she has had no further seizures except for some of those questionable events." Tr. at 191. The statement made by the physicians who treated Maggie in August 1975 also supports the conclusion that her seizures were transient. This statement noted that "the patient's seizures were most likely secondary to the pertussis vaccine" and that "children with microcephaly and some brain damage were unusually susceptible to this vaccine." Ex. F at 1-2. The treating physicians declined to give Maggie any anticonvulsive medications. The special master inferred that the treating physicians considered Maggie's seizures to be transient. Because the special master drew a plausible inference from the discharge statement and based his conclusion on relevant expert testimony, we hold that the conclusion that Maggie did not suffer from a compensable residual seizure disorder was not arbitrary or capricious.

Moreover, the special master's finding that Maggie did not experience the sequela of a residual seizure disorder should be upheld. The clinical history suggests that each of the subsequent seizure-like occurrences resulted from unrelated causes, including upper respiratory infection and pneumonia. Likewise, the expert testimony supports the special master's decision. Dr. Slater testified that the seizures were transient and the subsequent seizure-like occurrences



were of questionable origin. Dr. Evans testified that because the seizures were brief, they did not cause Maggie's subsequent neurological problems. Thus, there is ample evidence in the record to support the decision.

It is true that the findings that Maggie neither sustained a residual seizure disorder nor suffered its residual effects depend on each other to a degree. The special master's theory was that even though Maggie had seizures which were immediately secondary to the DPT vaccination, they were ultimately related to her underlying condition. Thus, because of her underlying neurological condition, he was able to conclude that the subsequent episodes were not primarily related to the DPT vaccination and that the seizures on August 19, 1975 were not sufficient to establish a compensable table injury. Without regard to whether we would have drawn the same inferences or reached the same conclusions, this theory is both lawful and reasonably based on the evidence in the record.[3]

## VI

The special master found that Maggie was microcephalic prior to August 18, 1975 so that she could not have sustained an encephalopathy as a result of the vaccination. The special master reached this conclusion by defining microcephaly as "a head size smaller than two standard deviations below the mean

[3] It is not entirely clear why the special master decided the case on this basis. Arguably, the special master could have decided that the respondent proved that the injuries were caused by an unrelated condition rather than deciding that the petitioner failed to make a prima facie case. Nonetheless, we conclude that the decision is rationally based upon a consideration of the entire record.

for a child of the same sex and age."[4] Order at 6. Two standard deviations from the mean is approximately at the 2.5 percentile. Thus, because Maggie was in the second percentile at birth, she was microcephalic prior to the vaccine. Petitioners contend that the special master arbitrarily chose the strictest definition of "microcephaly" for which testimony was reached.

Each of the experts that testified in this case acknowledged that this definition was accepted by the medical profession. Both Dr. Slater and Dr. Evans testified that there was no uniformly accepted definition of microcephaly. Dr. Slater cited three medical textbooks—two of which defined microcephaly as a head size smaller than two standard deviations from the mean and one defined it as three standard deviations from the mean. When asked about Maggie's condition prior to the vaccination, Dr. Slater testified that "[s]omething was clearly happening to the child before. Whether it was clear-cut secondary microcephaly depends on whether we are going to go with two or three standard deviations." Tr. at 179-80. Dr. Evans defined microcephaly as a head size at or below the second percentile. He testified, however, that a common definition in the field was a head size more than two standard deviations from the mean. Dr. Kitts also testified that the definition of microcephaly is a head size that is more than two standard deviations from the mean and that this was the gen-

[4] In finding that Maggie had a preexisting injury, the special master also relied on the discharge statement made by Maggie's treating physicians following her August 1975 hospitalization. The statement that "children with microcephaly and some brain damage [are] unusually susceptible to this vaccine" is a clear indication that these doctors considered Maggie to be microcephalic prior to the vaccination.



erally accepted definition. Hence, the special master's conclusion that a head size smaller than two standard deviations from the mean is the most commonly accepted definition of microcephaly is consistent with the expert testimony in the record.[5]

Because Maggie's preexisting injury precluded the vaccination from being the cause of the encephalopathy, the special master proceeded to address the issue of whether her preexisting injury was significantly aggravated by the vaccination. The Vaccine Act defines "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C.A. § 300aa-33(4). This court has devised a four-step evaluation, *see Misasi v. Secretary of HHS*, 23 Cl. Ct. 322, 324 (1991), which the special master applied to determine that the DPT vaccination did not significantly aggravate the preexisting microcephaly. In *Misasi*, this court held:

> To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's

[5] Both Drs. Kitts and Slater testified that it would take several weeks for a brain injury to cause a person's head size to fall off the growth chart. Thus, the fact that Maggie's head size was below the second percentile on August 20, 1975 would mean that she was microcephalic prior to the vaccination unless the most narrow definition, three standard deviations from the mean, were adopted.

condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered.

*Misasi*, 23 Cl. Ct. at 324.

The special master found that prior to the DPT vaccination, Maggie was microcephalic even though she showed few signs of having neurological problems. He found that she is currently severely mentally and physically disabled.

In his prediction of what Maggie's condition would have been if she had not received the vaccine, the special master concluded (1) that there was a greater than 90% likelihood that she would have been mentally retarded; (2) that the hip dislocations and sublaxations were congenital; and (3) that she might have developed cerebral palsy. Each of these conclusions is supported by expert testimony and medical literature.[6]

In reaching the critical issue, whether it was more likely than not that the current condition was significantly worse than the predicted condition, the special master determined that it was necessary to focus on the events occurring in close temporal relationship with the vaccination. Since petitioner pursued this case as a table case, the first manifestation of the significant aggravation must have occurred within the time period after the vaccine administration set forth in the Vaccine Injury Table. 42 U.S.C.A. § 300aa-11(c)(1)(C)(i).

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[6] Petitioner contends that the hip dislocations and sublaxations were caused by her cerebral palsy. Even if this were true, it would be irrelevant for purposes of this action because the special master concluded that the cerebral palsy was not caused or aggravated by the DPT vaccination.



The special master concluded that the two manifestations of complications resulting from the vaccine —projectile vomiting and the seizures—were insufficient to show that Maggie's condition deteriorated as a result of the vaccination. He considered the projectile vomiting to be inconclusive because it had become a chronic problem associated with the excess accumulation of mucus. Accordingly, there was no reason to believe that it was uniquely related to the vaccine. Furthermore, the special master concluded that the seizures, although perhaps immediately secondary to the vaccination, were not an indication that the vaccination resulted in permanent neurological damage. There is simply no evidence that these transient seizures were a sign of permanent brain damage.

Moreover, there was testimony suggesting that Maggie's entire clinical history is typical for a person with a condition similar to Maggie's who did not have vaccine complications. Dr. Evans found her clinical course to be "typical for any other child that had cerebral palsy, microcephaly, mental retardation and epilepsy" without any DPT complications. Tr. at 227. Based upon all evidence in the record, we conclude the special master's decision, supported by Dr. Evans' testimony, was not arbitrary.

## VII

Petitioner's objections to the special master's decision was overruled. The Clerk shall enter judgment for respondent in accordance with the special master's August 16, 1991 decision.

/s/ James T. Turner
JAMES T. TURNER
Judge

**APPENDIX C**

IN THE UNITED STATES CLAIMS COURT
OFFICE OF THE SPECIAL MASTERS

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No. 90-692V

MARGARET WHITECOTTON, by her
next friends, KAY WHITECOTTON and
MICHAEL WHITECOTTON, PETITIONERS

*v.*

SECRETARY OF THE DEPT. OF HEALTH AND
HUMAN SERVICES, RESPONDENT

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[Filed Aug. 16, 1991]

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DECISION

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*BAIRD, Special Master*

Petitioners seek compensation under the National Vaccine Injury Compensation Program [1] [hereinafter

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, *as amended*, 42 U.S.C.A. § 300aa-1 *et seq.* (West Supp. 1991). For convenience, individual sections of the Act will be cited herein without reference to 42 U.S.C.A. § 300aa.



the Program or the Act] for injury to their minor daughter Margaret Whitecotton (hereinafter "Maggie") allegedly resulting from a DPT (diphtheria, pertussis, and tetanus) vaccine administration on August 18, 1975.

Respondent filed a report which denies that petitioners are entitled to an award of compensation under the Program and asserts that Maggie's present condition is a result of a factor unrelated to the DPT vaccination, namely, chronic organic brain syndrome, a factor which preexisted the administration of the DPT vaccine.

A hearing limited to the issue of entitlement was held in Indianapolis, Indiana, on June 4, 1991.

## THE STATUTORY SCHEME

Under the Act, there are two separate means of establishing entitlement to compensation. If an injury listed on the Vaccine Injury Table found at 42 U.S.C. § 300aa-14(a) (hereinafter "Table") occurred or was significantly aggravated within the time period prescribed in the Table, then a qualified petitioner is entitled to compensation unless there is a preponderance of evidence that the injury or aggravation was due to factors unrelated to the administration of the vaccine. Compensation may also be awarded for injuries not listed on the Table or which are listed but occurred outside the time limits of the Table, but entitlement in such cases is dependent upon proof by a preponderance of evidence that the vaccine actually caused the injury complained of. In either case, the residual effects must have persisted for at

least six months, and unreimbursable expenses in excess of $1,000 must have been incurred as a result of the injury.

Petitioners have pursued their claim as a Table case. The petition alleged that Maggie suffered an encephalopathy and the onset of a seizure disorder[2] within three days following the administration of the DPT vaccine. Both "encephalopathy (or encephalitis)" and "residual seizure disorder" are Table-listed injuries for the DPT vaccine if the first symptom or manifestation of onset thereof appeared within three days following vaccination. Additional requirements for a residual seizure disorder are set out in § 14(b)(2) of the Act: The petitioner must not have suffered a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102° before the first seizure or convulsion following the administration of the vaccine and, within one year after the administration of the vaccine, two or more seizures or convulsions unaccompanied by fever or accompanied by a fever of less than 102° must have occurred.

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[2] Actually, the petition does not allege that Maggie suffers from a Table residual seizure disorder. It alleges that Maggie suffers from a "post-vaccine encephalopathy that presented with seizures twenty-four hours after the vaccination." Petition at para. 5. In their opening statement at the hearing, however, petitioners argued, based on comments the court made at an early off-the-record status conference, that a Table residual seizure disorder did exist and moved for summary judgment on that issue. The motion was denied, but the court considered the issue of whether a Table residual seizure disorder existed to be before the court.



## DISCUSSION

### a. Table residual seizure disorder

It is undisputed that Maggie had a series of clonic seizures on August 19, 1975, and that her temperature was below 102° at the time. Based on the testimony of Maggie's mother, the court also considers it more likely than not that Maggie had similar seizures on the evening of August 18. This is sufficient to allow[3] a finding that Maggie suffered the onset of a Table residual seizure disorder if she did not have and seizures prior to August 18, 1975, and the residual effects of the seizures recorded on August 19 continued for at least six months.[4] There is some question in the record, however, as to each of those elements.

The possibility of prior seizures is raised in a note in the hospital records of August 20, 1975, wherein

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[3] Section 14(b)(2) provides that a petitioner "may"—not "shall"—be considered to have suffered a residual seizure disorder if the conditions of the section are met. This means that there can be no finding of a Table residual seizure disorder unless those conditions are met, but it does not compel a finding of such an injury if they are.

[4] This conclusion is based on a literal reading of § 14(b)-(2)(B). Congress may have intended, however, that seizures occurring during the Table period should be considered as a unit and that the Table requirement is not satisfied unless at least one additional seizure with a temperature of less than 102° occurs outside the Table period and more than six months after the vaccination. This would be consistent with the requirement that the residual effects or complications continue for at least six months—the residual effects of a seizure disorder being more seizures.

the treating physician, Dr. Stanley Wissman, recorded his impression as follows: "Post-immunization seizures, [with] possible seizures earlier (leg jerks?)."[5] Considering the testimony of Maggie's mother concerning those jerks and the testimony of the expert witnesses with respect thereto, the court is of the opinion that it is more likely than not that the leg jerking which occurred prior to August 18, 1975, was benign myoclonic sleep jerking and not seizure activity. Therefore, there is not a preponderance of evidence that Maggie had seizures prior to receiving the DPT shot on August 18.

Maggie did not have additional seizures for a considerable period of time after August 19, 1975. She became very still, flaccid, and pale on the evening of February 24, 1976, and, because of her prior seizures, was hospitalized for 10 days with the suspicion of possible seizures. However, an EEG taken on the day after admission was normal and she had no seizures while in the hospital. This led the treating personnel to conclude that she "probably had acute episodes of upper airway obstruction by large amounts of mucus and tenacious sputum."[6] In January 1977, Maggie developed a fever of about 104° in connection with an upper respiratory infection and had what was diagnosed as a febrile convulsion.

An episode similar to the February 1976 episode occurred on August 28, 1979. Maggie suddenly went limp and became dusky and her eyes were rolling. Her mother took her to the emergency room where she threw up mucus on several occasions. She was admitted to the hospital for observation, but did not

[5] Exhibit F to petition (Ex.) at 8.

[6] Ex. H-3 at 2.



have any further problems. A chest x-ray suggested pneumonia in the left lung. She was given medication for pneumonitis and discharged. It was thought that her initial problem had probably been choking secondary to mucus in the throat.

Maggie had a grand mal seizure on March 21, 1980, the day after receiving a DT (diphtheria and tetanus) shot. She was taken to the hospital, where her temperature was recorded at 102°. Because she had a high leukocyte count, she was put on ampicillin. She was also given phenobarbital. That was the only time Maggie has been given anti-seizure medication. According to Mrs. Whitecotton, Maggie had focal seizures when she was in the early school grades, but she has not had any seizures in recent years. Gerald E. Slater, M.D.,[7] the pediatric neurologist who testified for the petitioners was unable to state to a reasonable degree of medical certainty that Maggie suffers from a Table residual seizure disorder. Under examination by the court, he referred to her seizures following the vaccination as "transient" and to her subsequent seizure history as "questionable."[8]

Based on the clinical history and on the expert testimony, the court is unable to conclude that Maggie "suffered the residual effects or complications of [a seizure disorder] for more than six months after the administration of the vaccine," § 11(c)(1)(D)(i), even though she had more than two seizures unaccompanied by fever or accompanied by a fever of less

[7] For the past two years, Dr. Slater has practiced both pediatrics and pediatric neurology in Glenwood Springs, Colorado. Between 1978 and 1989, he was a staff pediatric neurologist at the University of Minnesota.

[8] Tr. at 191.

than 102° in the 48 hours following the vaccination. Further, the evidence is clear that she does not presently have a compensable residual seizure disorder.

b. Table encephalopathy

1. As an original injury

It was the opinion of the physicians who treated Maggie during her hospitalization in August 1975 that she had suffered a post-immunization encephalopathy. The discharge diagnosis read: "(1) Microcephaly. (2) Postimmunization encephalopathy with seizures."[9] The discharge summary went on to state:

> It was thought that the patient's seizures were most likely secondary to the pertussis vaccine which she had received earlier in the day. It was Dr. Drew's feeling that children with microcephaly and some brain damage were unusually susceptible to this vaccine. It was decided to not start this child on any anticonvulsive medications at this time. The child will be followed by Dr. Drew in his office for any further seizure difficulty or any other evidence of CNS dysfunction associated with the microcephaly.[10]

It is reasonable to infer from the discharge diagnosis and this statement that at least some of the treating physicians (1) considered Maggie to be microcephalic; (2) thought that she might have preexisting brain damage; (3) considered her seizures to have been immediately secondary to the DPT vaccine but ultimately evidence of CNS dysfunction as-

[9] Ex. F at 1.

[10] Ex. F at 1-2.



sociated with microcephaly; (4) thought that her seizures might prove to be transient; and (5) were more concerned about her microcephaly—than about the post-immunization encephalopathy—as a potential cause of further CNS dysfunction.

When Maggie became microcephalic and the significance thereof—as contrasted to the significance of any damage related to the vaccination—were the primary points addressed by the expert witnesses. Dr. Slater did not define "microcephaly" but pointed out that there is no uniformly accepted definition of the term in the medical community. He cited three sources, two of which defined the term as more than two standard deviations below the mean, and one of which defined it as more than three standard deviations below the mean. Owen B. Evans, Jr., M.D.,[11] who testified for the respondent, did define the term and explained the significance of small head size:

> These height, weight and head circumference measurements are used as screening tools for clinicians, nurses and others to identify patients at risk and who are low in weight, who are short in height, who have small heads, . . .
>
> You will notice that some of them only go down to the fifth percentile. That is, many people believe that if somebody is below the fifth percentile they are very suspect and should be referred for further evaluations. Other authors believe the third percentile is a reasonable cut-

[11] Dr. Evans, who is board certified in pediatrics and pediatric neurology, is a professor in and chairman of the Department of Pediatrics and chief of the Division of Pediatric Neurology at University of Mississippi Medical Center, Jackson, Mississipi.

off for very suspect people. Others believe that two standard deviations, and yet another group will say the second percentile.

The point is that somebody with a small head when compared with the normal population is very much at risk of having developmental disabilities.

Now, the two standard deviations is going to fit . . . between the second percentile and the third percentile because it is about 2.5 percentile.

My definition of microcephaly is someone who is at the second percentile or less. If it is just below it or on it or what have you, that is a small head. . . .[12]

Having reviewed the sources cited at the hearing and consulted another source which has been cited previously by this court,[13] the court adopts what it finds to be the most commonly accepted definition of microcephaly, namely, a head size smaller than two standard deviations below the mean for a child of the same sex and age. By that definition, as pointed out by Dr. Evans, a child whose head size is at the second percentile is microcephalic, since the cutoff for two standard deviations is above the second percentile.[14]

Applying this definition to the facts presented in this record, the court finds that Maggie was at least

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[12] Tr. at 243-44.

[13] Gerald M. Fenichel, Clinical Pediatric Neurology 369 (1988).

[14] Dr. Evans cited the following sources, which support his testimony: Behrman & Vaughan, Nelson Textbook of Pediatrics 26 (13th ed. 1987); G. Kimble, How to Use Statistics 124 (1978). Dr. Slater acknowledged that the Behrman and Vaughan text is authoritative.



borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot on August 18, 1975. Maggie's head size at birth was 12.5 in.,[15] which converts to 31.75 cm. on her growth record.[16] Both Dr. Slater and Dr. Evans testified that this was right at the second percentile. Her head size stayed practically on the second percentile curve through three months of age, but dropped below that curve by August 20, the date of her hospitalization. This was noted in the discharge summary, "OFC was 37 cms., which is below two standard deviations from the norm," [17] and accounts for the diagnosis of microcephaly.[18]

In the succeeding months, Maggie's head growth fell further behind the norm for a girl of her age. Since the size of the head in a child is indicative of the size of the brain, the court is persuaded by this evidence and by the testimony of the neurologists that Maggie had suffered an encephalopathy sometime prior to the administration of the DPT vaccine on August 18, 1975. Dr. Slater acknowledged on several occasions in his testimony that "[s]omething was clearly happening to the child before [the DPT shot]. Whether it was clear cut secondary microcephaly depends on whether we are going to go with two or

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[15] Ex. B at 11.

[16] Ex. C at 5.

[17] Ex. F at 1. The measurement appears to have been taken on August 20. Ex. F at 5.

[18] A second head measurement taken during the hospitalization was 36.5 cm. Ex. F at 7. If this measurement was accurate, then Maggie's head may not have grown at all since it was measured a month earlier.

three standard deviations." [19] In his report filed prior to the hearing, Dr. Slater stated:

> It is the growth of the brain which promotes the growth of the skull. Her recorded head circumferences would indicate that her brain grew along its normal curve, albeit small, through the first three months of life. She then suffered impaired brain growth, and her head circumference fell off its normal curve. This is termed secondary microcephaly, and *implies a post-partum injury to the brain, at or near three months of age.*" (Emphasis added.)[20]

It was Dr. Evans opinion that Maggie suffered brain injury prior to birth, as evidenced by her microcephaly. Whether the injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975. Her original encephalopathy was not a Table injury which followed the August 18 DPT shot.

2. As a significant aggravation of a preexisting injury

The petitioners did not allege that a preexisting encephalopathy was significantly aggravated within three days of the August 18, 1975 DPT vaccination,

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[19] Tr. at 179-80. *See also* Tr. at 187 and 201.

[20] Ex. L at 1-2. In his testimony, Dr. Slater left the door open to an earlier injury date. He stated that it would take from several weeks to several months for head trauma to result in microcephaly. He also stated that there was nothing in Maggie's head growth chart inconsistent with an injury late in gestation or during the perinatal or neonatal periods.



but in light of the record and the court's findings on the injuries which were alleged, consideration must be given to the question of whether Maggie's preexisting encephalopathy was significantly aggravated during that period. If it were significantly aggravated, then that would give rise to a presumption of entitlement to compensation.

The term "significant aggravation" is defined in § 33(4) of the Act as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." The concept of significant aggravation is discussed in the legislative history as follows:

> The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intends that the time periods set forth in the Table apply to the significant aggravation in order for causation to be deemed to exist (e.g., a significant deterioration of a seizure disorder after DPT vaccination must first become manifest within three days of the vaccination).

H. R. Rep. 908, 99th Cong., 2nd Sess. Pt. 1 at 15-16, reprinted in U.S. Code Cong. & Admin. News 6344, 6356-57.

It has been held by this court that

> To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered.

*Misasi v. Secretary of HHS*, No. 90-400V, slip op. at 3-4 (Cl. Ct. June 7, 1991). Each of these elements will be addressed in turn.

(1) Condition prior to the administration of the vaccine

Prior to the August 18 shot, Maggie was microcephalic. Beyond that, there were only some hints that Maggie might have neurologic complications. For example, she first rolled over from her stomach to her back at two weeks of age, which is very early. Dr. Evans testified that early rolling over is usually associated with spasticity, but there is no evidence of the observation of early spasticity in the records,[21] and the photographs introduced at the hearing[22] do

[21] Maggie's early pediatric records are no longer available. All that exists is a letter from an associate of her pediatrician which indicates that Maggie was "seen at 3 weeks, 6 weeks, 2 months, 3 months and examinations were normal." Ex. D.

[22] Ex. O-1 through O-9.



not show obvious signs of spasticity, so the significance of the early rolling over is questionable. D. S. Hwang, M.D., who was Maggie's treating physician at the time of her 1979 hospitalization, noted that she "has had difficulty swallowing since birth."[23] Mrs. Whitecotton denied the accuracy of that note, but the court considers it credible. Dr. Evans testified that "children with cerebral palsy and mental retardation often present with feeding difficulties because of the poor coordination of all their musculature, including that of sucking and swallowing."[24]

(2) Current condition

Currently, Maggie is severely disabled both mentally and physically. She has cerebral palsy and has required surgery for hip and joint problems. She is nonambulatory. Her vocabulary is very limited. While she is able to provide some assistance in dressing, she is, for all practical purposes, totally dependent on others for her needs.

(3) Prediction of condition had the vaccine not been administered

The fact that there was little evidence of complications of microcephaly prior to August 18, 1975, does not mean that Maggie would have developed normally. It is not unusual that a neurological problem does not become evident until the central nervous system of an infant or child matures to the point where developmental milestones are missed or delayed. Hypertonicity generally develops gradually.

[23] Ex. H-12 at 3.

[24] Tr. at 209.

Ellen Louise Kitts, M.D.,[25] testified on behalf of the petitioners. She acknowledged that cerebral palsy typically becomes evident between six months and one year of age. Mental retardation may not become evident until much later. Based on her microcephaly alone, the court is able to predict with a high degree of certainty that Maggie would have been mentally retarded even if the DPT vaccine had not been administered to her on August 18, 1975. Dr. Menkes states in his textbook that nearly 100% of microcephalic children are mentally retarded.[26] Dr. Fenichel states that "almost every individual with microcephaly is mentally retarded."[27] Dr. Evans testified that only about 7.5% of microcephalics have normal intelligence. Thus, there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone.

The court is also able to predict with a high degree of certainty that Maggie would have experienced the hip dislocations and sublaxations which she has experienced, absent the DPT shot. These problems are consistently referred to in the records as congenital in nature, and there is no basis for concluding that they are not.

The evidence relating to Maggie's cerebral palsy is not as clear. Both Dr. Slater and Dr. Evans agreed

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[25] Dr. Kitts is a physician who specializes in pediatric physical medicine and rehabilitation. She is board certified in both pediatrics and physical medicine and rehabilitation. She resides in Wheeling, West Virginia, where she serves as medical director of the Easter Seal Rehabilitation Center.

[26] John H. Menkes, Textbook of Child Neurology 247 (4th ed. 1990).

[27] Gerald M. Fenichel, *supra*, n.13.



that, according to the literature, in most cases the etiology of cerebral palsy is never determined. However, Dr. Slater testified that mental retardation is associated with microcephaly, but that gross motor problems are not, while Dr. Evans testified that both mental retardation and motor impairments—including cerebral palsy—are typically associated with microcephaly. It appears from reviewing other sources[28] that cerebral palsy may result from primary or secondary microcephaly and that it always follows perinatal brain injuries. Thus, it is reasonable to conclude that Maggie's cerebral palsy may have occurred without any involvement of the DPT vaccine and that there is no way to know for certain whether the DPT vaccine caused or aggravated it.

(4) Comparison of current condition with predicted condition had the vaccine not been administered

In conducting this aspect of the analysis, it is both necessary and appropriate to focus on the events which occurred in close temporal relationship to the vaccination to see what light they shed on the issue. It is necessary in a Table case because, in order to find a Table aggravation, the Act requires that the aggravation become evident during the Table period. It is appropriate in all cases because the timing of the onset of deterioration in condition following a vaccination bears on the issue of causation.

Maggie had seizures following the vaccination. Seizures are sometimes indicative of ongoing brain damage, but not necessarily so. The treating physi-

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[28] Gerald M. Fenichel, *supra*, n. 13, at 370-72; John H. Menkes, *supra*, n. 26 at 245-47.

cians diagnosed a "postimmunization encephalopathy with seizures," so they must have associated the seizure activity with at least an acute encephalopathy. Mrs. Whitecotton testified that Maggie projectile vomited while in the hospital following the vaccination. Projectile vomiting is sometimes associated with the brain swelling which may accompany encephalopathy, so this is additional evidence that an encephalopathy may have been occurring at that time. However, Mrs. Whitecotton testified further that projectile vomiting became a chronic problem associated with the excess accumulation of mucus, so its significance is uncertain. She never mentioned the problem to Maggie's doctors.

Other than these symptoms, there is no evidence that Maggie suffered permanent neurological damage which significantly aggravated her preexisting condition in close temporal relationship to the vaccination. The discharge diagnosis included the following physical examination results:

> The HEENT examination appeared to be normal. The remainder of the physical examination was unremarkable. Neurological examination revealed the patient to be alert, follow objects with her eyes past midline, trying to reach for the objects with both hands. Motor examination revealed good activity in all motor groups. The tone, though difficult to assess, appeared to be normal. Muscle stretch reflexes were normoactive and equal bilaterally.[29]

There is no indication in this report that Maggie's neurological condition had deteriorated or was deteriorating.

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[29] Ex. F at 1.



Mrs. Whitecotton testified that Maggie lost some developmental milestones following the shot—she became slouchy and lost the ability to raise her feet up in front of her hands—and that other milestones became "scattered."[30] She also testified that Maggie became fretful after the shot. However, there is no evidence of any of this in the medical records. The pediatric records are unavailable. When Maggie was hospitalized in February 1976, it was noted that she had started gagging herself and vomiting for attention (she would stop when she was picked up) four months earlier, at the age of six months. This activity had ceased two months prior to admission. Her growth had been slow, but it had never stopped. She began sitting at four to five months of age and was now able to crawl and, to some extent, pull herself up. There was no head lag. She grasped, tracked, supported her weight, and supported herself in a prone position. She was thought to be somewhat hypertonic intermittently. The weight of the evidence is that there was no dramatic change in Maggie's condition following the DPT shot. Her development was slow but sure, and the onset of hypertonicity was gradual. There is nothing to distinguish this case from what would reasonably have been expected considering her microcephaly.

It was Dr. Kitt's opinion that all of Maggie's problems flow from a single source. "[T]here was a brain injury that caused the microcephaly that caused the seizures that caused the cerebral palsy."[31] "It is a single brain injury that caused all of the above, and microcephaly is one of the manifestations of that

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[30] Tr. at 26.

[31] Tr. at 118.

brain injury."[32] Dr. Kitts attributed all of Maggie's problems to the DPT vaccine, but, in light of the fact that the microcephaly predated the DPT vaccination, that is not a reasonable conclusion.

Dr. Evans also attributed all of Maggie's problems to a single source—prenatal chronic organic brain syndrome. He found her clinical course to be typical "for any other child that had cerebral palsy, microcephaly, mental retardation and epilepsy" without any DPT complications.[33] He stated that 36% of the infants who are going to develop neurologic disorders appear neurologically normal at four months of age. Dr. Kitts testified that cerebral palsy frequently does not manifest itself prior to six months of age.

It appears from the record as a whole that there was a single brain injury that caused all of Maggie's problems. Maggie was born with a brain defect, and there was nothing that occurred in temporal relationship to the DPT vaccination which indicates that it is more likely than not that the vaccine permanently aggravated her condition. It may have caused a temporary encephalopathy evidenced by transient seizure activity, but the seizures did not continue and there was no dramatic turn for the worse in her condition indicating a permanent aggravation of her brain disorder. Nor were there clearly any acute signs of encephalopathy other than the seizures. As she matured neurologically, the complications of whatever caused her microcephaly gradually manifested themselves, just as they do in a typical case involving congential brain damage.[34] Thus, there is no basis for

[32] Tr. at 119.

[33] Tr. at 227.

[34] Dr. Kitts testified that cerebral palsy frequently does not manifest itself prior to six months of age.



implicating the vaccine as the cause of any aspect of her present condition.

## FINDINGS OF FACT

The following findings of fact are supported by a preponderance of the evidence:

1. Maggie Whitecotton was born on April 22, 1975, with a brain disorder evidenced by microcephaly which became more pronounced by the age of four months.

2. On August 18, 1975, the DPT vaccine was administered to Maggie in Indiana.

3. Maggie suffered transient seizure activity within three days following the administration of the DPT vaccine, the residual effects or complications of which did not continue for six months.

4. Maggie did not suffer a permanent encephalopathy within three days following the said administration of DPT vaccine.

5. No significant aggravation of Maggie's underlying brain disorder was manifested within three days following the said administration of the DPT vaccine.

6. The DPT vaccine did not cause a significant aggravation of Maggie's underlying condition.

## CONCLUSION OF LAW

Petitioners are not entitled to an award of compensation under the Program.

In the absence of a motion for review filed pursuant to RUSCC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

/s/ Paul T. Baird
PAUL T. BAIRD
Special Master

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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No. 92-5083

MARGARET WHITECOTTON, by her next friends,
KAY WHITECOTTON and MICHAEL WHITECOTTON,
PETITIONERS-APPELLANTS

*v.*

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

---

[Filed Apr. 29, 1994]

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ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLEE, and a response thereto having been invited by the court and filed by the APPELLANT, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further



ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on May 6, 1994.

Circuit Judge NIES would rehear the appeal.

FOR THE COURT,
FRANCIS X. GINDHART
Clerk

By /s/ Diane M. Frye
DIANE M. FRYE
Chief Deputy Clerk

Dated: April 29, 1994

cc: JOHN S. CAPPER, IV
KAREN P. HEWITT

WHITECOTTON V HHS, 92-5083
(CLM—90-692 V)

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No. 94-372

In The

# Supreme Court of the United States

October Term, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,

*Petitioner,*

v.

MARGARET WHITECOTTON, ET AL.,

*Respondents.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## BRIEF IN OPPOSITION

ROBERT T. MOXLEY
GAGE & MOXLEY
Attorneys at Law
623 West 20th Street
Post Office Box 1223
Cheyenne, Wyoming 82003-1223
Phone (307) 632-1112

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

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**No. 94-372**

**In The**

# Supreme Court of the United States

**October Term, 1994**

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,

*Petitioner,*

v.

MARGARET WHITECOTTON, ET AL.,

*Respondents.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## BRIEF IN OPPOSITION

Respondent, Margaret (hereinafter "Maggie") Whitecotton, by and through her parents and next friends, Kay and Michael Whitecotton, respectfully prays that this honorable Court deny the request of Donna E. Shalala, the Secretary of Health and Human Services, to review the order and judgment of the United States Court of Appeals for the Federal Circuit, entered on the 15th day of February, 1994 (*rehearing denied*, April 29, 1994), reversing the judgment of the United States Court of Federal Claims.

## INTRODUCTION

The government's rendition of the facts in this case is egregiously stilted. The result is a complete misrepresentation of the meaning of the rule articulated below by the court of appeals. The government would have this case to be a "significant aggravation" vaccine case by making the assertion that Maggie Whitecotton had a preexisting disorder, an "organic brain syndrome." In fact the so-called preexisting condition is completely speculative.

The idea of "preexisting condition" under the Vaccine Act goes cheek-to-jowl with the idea of "factors unrelated." But the instant case was a classic case of vaccine injury. The post-vaccine encephalopathy was manifest by multiple seizures within the first half-day, early in the 72-hour "window" which the Vaccine Injury Table adopts from the majority of medical authorities.[1] The contemporaneous diagnosis of Maggie's condition is that the injury is indeed a DPT-induced encephalopathy.

The defense was also "classic" – that is, overly adversarial and legally misdirected.[2] The government

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[1] As noted by the government, the Act directed the Secretary of DHHS to establish the Program "to achieve . . . optimal prevention against adverse reactions to vaccines." (Petitioner's Brief at page 4.) A recent report generated under this thrust of the Act, from the Institutes of Medicine (IOM), accepts a seven-day window of vulnerability to permanent neurological injury. DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis, National Academy Press, 1994

[2] "Respondents have . . . mounted defenses incompatible with a no-fault system of compensation." House Conf. Rep. No. 101-386, 101st Cong., 1st Sess., page 513; *reprinted* 4 USCCAN 3112, 3116 (1989).



sponsored an expert witness who does not even **believe** in DPT vaccine injury. This expert, Dr. Evans, testified that the contemporaneous dianosis of DPT injury in August of 1975 must have been made (paraphrasing) "because back then they **did** believe in it."[3] The expert's opinion relied upon questionable factors – **not** utilized in the special master's reasoning to deny compensation. Dr. Evans also admitted that the seizures and other features of Maggie's illness are not typical for the "organic brain syndrome" he postulated as a "preexisting" condition.

Dr. Evans testified that Maggie's growth chart figures were "very close," and that she would **not** be microcephalic by some accepted measures. This latter point is conclusive. It is fatal to the special master's statistical analysis. Moreover, "microcephaly" is not a disease entity, it has no natural course, and Dr. Evans stated that most cases are worse than the instant one. Seizures are not a classic or stereotypical symptom. Nor is cerebral palsy.

The inappropriate and illogical stretch of the facts to find a "preexisting condition" is the essence of the error in the Office of Special Masters of the United States Court of Federal Claims. There was no preexisting condition, certainly not such an entity as is contemplated by the express language and legislative intent of the Vaccine Act. A preexisting condition under the Act must be an "illness," a "disability," an **already manifest** lack of good health. Under the Vaccine Act, to significantly aggravate

---

[3] Prior to the recent report referenced in footnote 1, *supra*, the Secretary insisted that there was no solid scientific evidence to indicate that DPT could cause permanent injury.

a "preexisting condition" there must be **greater** disability, pain or illness[4] (emphasis added). There can not be "greater" illness unless there is **already** illness.

The "organic brain syndrome" – ***and*** the "microcephaly" which the government asserted as its distinguishing feature – is HYPOTHETICAL. As a result, the plain language of the Vaccine Act[5] prohibits reliance upon such a "factor unrelated." Indeed, the new feature of the rule below – an emminently correct rule – is that the Court of Appeals has finally recognized and enforced the clear and explicit statutory limitations upon the affirmative defense of "factors unrelated to the administration of vaccines."

The government would have the courts in this case to ignore the substantial difference between "borderline microcephaly" and the full-blown, overt condition. True, clinically significant microcephaly signals a complete lack of brain growth and development. But "borderline microcephlaly" is a condition which is not incompatible with normal growth and development, and all evidence indicates that Maggie Whitecotton was normal at the time of the shot which did her in.[6] In short, the government's case syllogism throughout herein has been essentially the absurd proposition that the child with a small head, small

---

[4] 42 U.S.C. § 300aa-33(4).

[5] The text of 42 U.S.C. § 300aa-13(a)(2)(A) is set forth at page 3 of Petitioner's Brief.

[6] Tests at the time of the first hospitalization for seizures indicated a demylinating process at work. This is a classic sign of vaccine injury, and of acute brain injury in general.



stature, and no other problems, is not entitled to compensation for a legally presumed vaccine injury, despite severe onset of brain injury symptoms within three days of a DPT vaccine.

The child's current treating physician testified at trial and supported the earlier, contemporanous diagnosis of a vaccine injury. Yet, the government and the special master worked, almost in concert, to defeat the claim. The egregious result below **compelled** the Federal Circuit Court of Appeals' articulation of a much-needed rule of caselaw,[7] one which does little more than to affirm the statutory presumption of causation. The only significance of the rule is that in doing so it overrules a long line of bad precedents and rules of decision in conflict with the express statutory language.

## ADDITIONAL STATUTORY PROVISIONS INVOLVED

The pivotal statutes which illustrate that the Court of Appeals decision is correct are principally found in the "Qualifications and Aids to Interpretation" to the Vaccine Injury Table set forth in 42 U.S.C. § 300aa-14(a)[8]

The pertinent provisions of the statute are the various definitions of "encephalopathy," and the provisions

---

[7] The typical review of vaccine cases is **exceedingly** deferential to the Office of Special Masters. *See, e.g., Phillips v. Secretary of DHHS*, 988 F.2d 111 (Fed. Cir. 1993).

[8] The Table is partially set forth at pages 3-4 of Petitioner's Brief.

of the statute (found at 42 U.S.C. § 300aa-13(a)(2)) reproduced in Petitioner's Brief, relating to the "factors unrelated."

The Petitioner has quoted that part of 42 U.S.C. § 300aa-14(3)(A) which defines "encephalopathy" as "any significant acquired . . . impairment of function of the brain." (Petitioner's Brief at page 4). Significant language also from that subsection states that "Among the frequent manifestations of encephalopathy are focal and diffuse nuerologic signs, increased intercranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions."

The provisions of 42 U.S.C. § 300aa-14(b)(4) state in pertinent part:

> "For purposes of paragraphs (2)[9] and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs."

It is the obvious import of 42 U.S.C. § 300aa-14(b)(3)(B) read together with sections 14(b)(3)(A) and 14(b)(4), that "encephalopathy" embraces seizures, and is conclusively shown by seizure activity.

The statute also creates a particular subspecies of encephalopathy, known as the "residual seizure disorder." The statute provides at 42 U.S.C. § 300aa-14(b)(2):

> "A petitioner may be considered to have suffered a residual seizure disorder if the petitioner ***did not suffer a seizure*** or convulsion . . . ***before***

[9] Subparagraph (2) relates to and defines "residual seizure disorder."



> ***the first seizure*** or convulsion ***after*** the administration of ***the vaccine*** involved ***and if*** . . .
>
> (B) . . . ***the first seizure occurred within three days*** after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine . . . "
> (Emphasis added.)

The four categories of possible factors unrelated in the "General Rule," 42 U.S.C. § 300aa-13(a)(2), are repeated at 42 U.S.C. § 300aa-14(b)(3)(B), which states: "The following qualifications and aids to interpretation ***shall apply to the Vaccine Injury Table*** in subsection (a)" (emphasis added).

The statute plainly sets forth the restriction, in "Table" cases, to these four classes of alternate cause:

> " * * * (3)(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy ***was caused by*** infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. ***If*** at the time a judgment is entered on a petition filed under section 2111 for a vaccine-related injury or death ***it is not possible to determine the cause***, by a preponderance of the evidence, of an encephalopathy, ***the encephalopathy shall be considered to be a condition set forth in the table*** . . . "
> (emphasis added)

## MISSTATEMENTS OF FACT WHICH BEAR UPON THE PETITION

Maggie Whitecotton cannot be said to have been born with, or to have acquired prior to her third DPT shot, "a condition known as microcephaly." (Petitioner's brief at 6.) While the defense asserts she was in the second percentile of head size at birth (Appendix B at 11a, Petitioner's Brief), she was not.[10] Even if accepted as true, this state of head growth does not constitute a "condition" as contemplated by the Vaccine Act. Nor does it support the findings of the special master. As noted by the Court of Federal Claims (Petitioner's Brief Appendix B at page 21a, fn 5): "she was microcephalic prior to the vaccination ***unless the most narrow definition, three standard deviations from the mean, were adopted.***"

The government implies throughout that Maggie Whitecotton did not "get markedly worse" (*see, e.g.*, the discussion at 14-15, Petitioner's Brief) after her third DPT shot. But in fact, "Maggie was healthy, developmentally and physically, until she received her third diphtheria-pertussis tetanus (DPT) vaccination . . . " (Decision of the Federal Circuit, Appendix A page 2a, Petitioner's Brief.) Today, Maggie is non-verbal, she has cerebral palsy, and is moderately mentally retarded. Her health most clearly deteriorated after her third shot. Her school-age booster shot induced a coma within twelve hours.

---

[10] Two "standard deviations" below normal is at the mid-point between the 2nd and 3rd percentile. The government has consistently confused "2 SD" with "2nd percentile."



## SUMMARY OF ARGUMENT

Quite plainly, there is no logic to the special master's initial denial of compensation (**even if** "ideopathic" conditions were fair game for "factors unrelated"). The logic would **always** be defective unless the so-called "most narrow" definition of "microcephaly" were used, **and** if the child's condition fit the full-blown microcephaly of that "most narrow"[11] category, *i.e.*, headsize smaller than three SD below the mean. The broader, loose definition of two SD from the mean is translatable into nothing more (nor more ominous) than "small head."

The "onset" of a condition under the Vaccine Act is the key to the Table presumption. The special master found that Maggie Whitecotton qualified for treatment under the concept of "residual seizure disorder." (Appendix C, Petitioner's Brief, page 27a.) But at any rate the case is a proper case for an award of the necessary compensation to emeliorate the consequences of an enduring encephalopathy.

The government postulates **absurd** consequences if the rule below is allowed to stand. The government begs this Court to restore the "integrity" of the Vaccine Program. In point of fact the rule below **brings** to the Program a much-needed integrity.

The government would have the courts to ignore the fact that the Vaccine Act is a compensation statute, one

---

[11] As it will appear, what Judge Turner termed the "most narrow" definition (which is more than 3 SD below the mean) is the only type of "microcephaly" with clinical significance to "inevitable" mental retardation.

with policy implications and objectives. The express intent of the Act is to dispense with close questions of causation. Yet no case could be closer than the instant case to an **actual** DPT injury. Moreover, the Act is intended to promote confidence in the mandatory immunization program via generous compensation of **apparent** vaccine injuries. The conclusion is obvious that the *Whitecotton* rule is mainstream compensation doctrine. It means nothing more nor less than that the express statutory language is to be honored. It is a long-overdue case which gives life to the heretofore ignored statutory presumption of injury by vaccine, injury "***associated with***[12] one . . . of the vaccines set forth in the Vaccine Injury Table."

It is undisputable that the special master in this case extrapolated the small head size (**standing alone**) of Maggie Whitecotton beyond the parameters of the medical testimony and the literature. The special master formulated his own impossible-to-defend medical opinion and prognosis. And thus, while the child actually had a head size prior to her encephalopathy (which occured in "table time" after the DPT shot, under the Vaccine Injury Table) which was between the second and third percentile of the population, the special master assigned her a prognosis of "90% inevitable" severe disability. The population itself puts the lie to this. It is impossible to sustain the notion that ninety per cent of the persons in the general

---

[12] This is the liberal definition of "vaccine-related injury" from 42 U.S.C. § 300aa-33(5) (emphasis added).



population with like head size to Maggie have such disability characteristics. And if the extrapolation of statistics were true, the population of mentally-retarded people – ninety percent of the people with small heads – would be enormous.

Finally, there is little substance to the argument that the *Whitecotton* case deserves *certiorari*. The case is an early case in the evolution of a new system. The fiscal concerns voiced are completely artificial. That is, the Act is a legal replacement for other government programs which **could** provide substantially the same benefits as are paid in "retrospective" cases to any disabled person whose guardian has the legal grasp and fortitude to seek these benefits from myriad agencies. The "prospective" cases under the Act are funded from a Trust Fund which is flush with monies generated by a tax on vaccines.

There is no conflict between the decision of the Federal Circuit and the mainstream of compensation law. Nor is there a misapplication of the statute itself. The government is simply piqued at the prospect of no longer having its way with vaccine-injured petitioners.

The government's desire to relitigate is in no wise a justification for the exercise of the supervisory jurisdiction of this Court. The clarification of the *Whitecotton* rule should take place in the trial forum, the traditional crucible of contested cases which provides the heat and fire in which the law is traditionally forged.

## STATEMENT OF REASONS FOR DENIAL OF CERTIORARI

### I. THE PETITION INCORRECTLY REPRESENTS THE FACTS AND LAW WHICH COMPELLED A FINDING bELOW IN FAVOR OF VACCINE INJURY COMPENSATION FOR THE BENEFIT OF MAGGIE WHITECOTTON

#### A. Maggie Whitecotton's So-Called State of "Microcephaly" Prior to the Shot Has No Medical Significance

Congress made the statement in the original legislative history that a condition of **ongoing** seizures "might legitimately be described as preexisting." House Rep. No. 99-908, 99th Cong., 2nd Sess. page 15, *reprinted*, 6 USCCAN 6344, 6356 (1986). Coupled with the characterization of preexisting conditions as "***events*** in the person's past medical history" (*Ibid.*, emphasis added), it is obvious that Congress was not speaking of mere potentialities. The focus of the Act is on **symptoms**.

The Special Master in this case equated a questionable, borderline microcephaly with a major, full-blown disorder. The special master ignored a marked discontinuity of development **and** head growth, post-vaccination. Special Master Baird's logic allowed him to depend **entirely**[13] upon the alleged "microcephaly" to

[13] Because the special master's ultimate reasoning rested completely on the headsize, the Federal Circuit did not have to address the showing made in a Rule 60(b) motion. This showing completely refuted the special master's findings of swallowing problems, as does the medical record taken as a whole. The



determine the presence of the "chronic organic brain syndrome." Special Master Baird's finding that the mental retardation was "inevitable" is purely a matter of his own statistical analysis of head size as the proof of the defense.

The special master's conclusion and reasoning was set forth in the Decision as follows:

> "The fact that there was little evidence of complications of microcephaly prior to August 18, 1975, does not mean that Maggie would have developed normally. It is not unusual that a neurological problem does not become evident until the central nervous system of an infant or child matures to the point where developmental milestones are missed or delayed. Hypertonicity generally develops gradually. Ellen Louise Kitts, M.D., testified on behalf of the petitioners. She acknowledged that cerebral palsy typically becomes evident between six months and one year of age. Mental retardation may not become evident until much later. ***Based on her microcephaly alone, the court is able to predict with a high degree of certainty that Maggie would have been mentally retarded*** even if the DPT vaccine had not been administered to her on August 18, 1975. Dr. Menkes states in his textbook that nearly 100% of microcephalic children are mentally retarded.[14] Dr. Fenichel states that

60(b) showing – as well as the pictures in evidence and the testimony of the current treating physician, a physiatrist – similarly refutes the idea that cerebral palsy or hip subluxations existed prior to the shot and its concomitant brain injury.

[14] Dr. Menkes' textbook is speaking of clinically categorized children, with headsize more than 3 SD below the mean.

"almost every individual with microcephaly is mentally retarded." Dr. Evans testified that only

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But there is no disputing that Maggie's headsize was on the borderline of **two** standard deviations below the mean, up until several months **after** the shot. The majority of authorities would see this as of little significance:

> "The word microcephaly is sometimes loosely used for a head which looks small, but is perhaps better restricted to patients with a maximal occipitofrontal head circumference ***smaller than three standard deviations below the mean*** for their age and sex." Brimblecome, Children in Health and Disease, page 489 (emphasis added).

*See also* Kemp, Current Pediatric Diagnosis and Treatment, Ninth ed., chapter 23, page 692 (defining microcephaly as "a head circumference three SD or more below mean for age and sex"); Rudolph, editor, Pediatrics, 17th ed., page 402 ("Most investigators have defined microcephaly as a occipital-frontal circumference (OFC) of less than three standard deviations (SD) below the mean for age and sex."); Pediatric Neurology, 3rd ed., Harper and Row, page 71 ("For standardization microcephaly is arbitrarily defined by a cranial circumference less than three standard deviations below the normal for age and sex."); Wasserman, Survey of Clinical Pediatrics, 7th ed., page 346 ("Microcephaly . . . the head circumference is always three standard deviations below the mean"); Signs and Symptoms in Pediatrics, Lippencott, Chapter 22, page 112 ("There is some disagreement about the clinical definition of microcephaly. The criterion of head circumference more than two standard deviations . . . has been used; measurements three or more standard deviations below the mean have also been recommended."); Differential Diagnosis in Pediatric Neurology, Lagos, page 209 ("Arbitrarily, true microcephaly is defined as a head circumference of minus three or less standard deviations below the mean for a certain age."); Green, Pediatric Diagnosis, 3rd ed., ("Microcephaly is the term applied when the head circumference is two or three standard deviations below the mean for age, sex, height and weight."); and Dorman, Developmental Medicine and Child Neurology, 1991, page 267, ("Microcephaly



> about 7.5% of microcephalics have normal intelligence. Thus, ***there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone.***" (Special Master's Decision, Petitioner's Brief, Appendix C, pages 37-38a)

The conclusion made by Special Master Baird (that 90% of "microcephalics" are mentally retarded) is proven wrong by a comparison between the actual number of people who are classified as mentally retarded, with the actual number of "microcephalic" people who **would** be mentally retarded under the loose definition adopted by the special master.

Statiticians use the *standard deviation frequency curve* to show how all head sizes vary from the average or "mean" size. The more the head size varies from "average normal," the higher the number that is used to define the deviation. The curve bases its variations on set percentages from the average, and the "Standard Deviations" (SD) begin at either +1 or -1, and continue in both the positive and negative directions until they reach 4 or 5 SD.

The *standard deviation frequency curve* always places 2½% of the total below the "-2 SD" point, which would be 25 people per 1000 population. *See*, Friedman, et al., Statistics, 2nd ed., Chapter 5, "Growth Charts," pp. 74-76, (W. W. Norton Co., 1991).

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has been variously defined as a head circumference more than two SD or more than three SD below the mean.").

All the major texts, government agencies, and private organizations recognize that three percent of the population of the United States may be classified as mentally retarded. The Special Olympics movement publishes a chart entitled "Brief Facts on Mental Retardation", utilizing data from the Association for Retarded Citizens. It begins[15] as follows:

**BRIEF FACTS ON MENTAL RETARDATION**

250 million persons (approximately) in the United States.

7.5 million persons with mental retardation in the United States.

100,000 babies are born in the United States each year with mental retardation.

The chart ends[16] with a statement of the distribution of mental retardation by age and severity (the proportions would not have changed), using 1980 figures:

**ESTIMATES OF RETARDATION BY AGE AND DEGREE**

| **1980 Estimate** | **All Ages** | **Under 21** | **Over 21** |
|---|---|---|---|
| General Population | 220 mil. | 85.8 mil. | 134.2 mil. |
| 3% General Population | 6.6 mil. | 2.6 mil. | 4.0 mil. |

[15] The entire chart was reproduced for the Federal Circuit.

[16] The chart also regards retardation as a separate entity, and states *inter alia* that "In the United States, mental retardation is . . . 9 times more prevalent than cerebral palsy."



**Mental Retardation Levels**

| | | | |
|---|---|---|---|
| Profound (IQ under 20) approx. 1½% | 99 thou. | 39 thou. | 60 thou. |
| Severe (IQ 21-35) approx. 3½% | 231 thou. | 90 thou. | 141 thou. |
| Moderate (IQ 36-50) approx. 6% | 396 thou. | 154 thou. | 242 thous. |
| Mild (IQ 51-70) approx. 89% | 5.9 mil. | 2.3 mil. | 3.6 mil. |

Reference-Association of Retarded Citizens – 1988

Special Master Baird stated in essence that "90% of all microcephalics are mentally retarded." He clearly made this statement after adopting the most broad definition of microcephaly (everyone below **-2 SD – 2½ per cent of the entire population**). What his holding means is that 22.5 people out of any group of 1,000 (90% of 25 = 22.5) are not only microcephalic, but mentally retarded as well. There is no sustaining this dramatic statement. The Special Olympics chart reveals that only 3% of our nation's population (30 individuals out of every group of 1000 people) are to be classified as mentally retarded, and this includes the vast majority who are only mildly mentally retarded. The special master must believe (by virtue of his erroneous statements) that 22.5 of every 30 of these individuals have small heads. This is ridiculous. The vast majority of the mentally retarded are physically normal and **they do not have small heads**. In order to render Special Master Baird's strong statement factual, one

would have to relate it to individuals with head size that falls into the -3 SD or even the -4 SD group. **Absolutely nothing can be assumed to be wrong with the people with non-visibly detectable smaller heads – such as Maggie's – who only border on the -2 SD group**. Most of the statistics concerning microcephaly have been compiled from clinical records involving only those who are ailing, and not from the entire spectrum of microcephalics. As shown by literature on the record,[17] those that were tested in normal life (in the public schools) showed no signs of below average intelligence, and some were even superior. It is only logical that people who are living a normal life would not be tested for retardation, even if is discovered that their heads measure a certain, statistically small size.

The Sells study notes a paucity of research regarding microcephaly in normal populations, and cites Nelson and Duetschberger (Dev. Med. Child Nuerol. 12:487, 1970) as a source of a 50% risk figure. The conclusion is obvious: Maggie Whitecotton had at least as much chance to be normal as she had to be disabled.

Therefore it was, and is, absurd to assign any credibility at all to the statistical game playing below. The vast majority of mentally retarded people are physically normal, and they don't have small heads. The DPT shot would appear to any layman, as it appeared to the diagnosing physicians, to be the culprit in Maggie's disability.

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[17] Sells, *"Microcephaly in a Normal School Population,"* Pediatrics, Vol. 59, No. 2 (February 1977)



Maggie Whitecotton is the type of child for whom the Vaccine Act was written. Even if a petitioner has an increased likelihood of injury, the proverbial "egg shell skull,"[18] there is no legal significance in that fact:

> "While it is true that some children, because of their physical condition, are more likely to react to a vaccine, vaccine reactions are not completely foreseeable. . . . And since State law requires that all children be immunized before entering school, most parents have no choice but to risk the chance – small as that may be – that their child may be injured from a vaccine." H.R. 99-908, page 6, *reprinted*, 6 USCCAN 6344, 6347 (1986).

### B. There Is No Defense to a Table Claim Except in the Enumerated Alternate Causes

The presumption created by the Table is given sway in the Act over **any** "factor unrelated" **except** the listed four. That is, if there is a Table Case, the factor unrelated must be clearly shown as the result of "toxins, trauma, infection or metabolic disturbance." Even then, there is only a "factor unrelated" in the absence of a contributory role for the vaccine. The statute is explicit in stating that a "Table" condition is to be found ("the encephalopathy

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[18] The unmistakable tone of the Petitioner's Brief is that previously compromised children are **immune** from vaccine injury.

***shall***[19] ***be considered to be a condition set forth in the table***") if it is not possible to determine by a preponderance of evidence whether the permanent encephalopathy results from the Table Time reaction or from the restricted list of factors unrelated. 42 U.S.C. § 300aa-14(b)(3)(B) (emphasis added).

The contrast between Sections 300aa-13 and 300aa-14 illustrates the point that an inborn condition is **irrelevant** in a Table Case (unless it is, by coincidence, the result of a **known** trauma, or the cause of a "metabolic disturbance"). To find this contrast, the court must compare the operative language which creates the two-step inquiries in these two sections.

The two-step inquiry for § 13 purposes is general, mandating first that the petitioner show "the matters required in the petition." Then, the determination is made that there is no proof of cause by factors unrelated. 42 U.S.C. § 300aa-13(a)(1)(A) and (B). It is necessary to focus on the modifier in subsection (2), to-wit: "***for the purposes*** of paragraph (1)," in contrasting the operative, modifying words, respectively in subsections (2)(A) and

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[19] The mandatory word "shall" in this subsection creates an ambiguity when it is contrasted with the language of its neighboring clause, 42 U.S.C. § 300aa-14(b)(2)(B), to-wit:

> "A petitioner ***may*** be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure . . . before the first seizure . . . after the administration of the vaccine . . . " (Emphasis added.)

Judge Turner of the Court of Federal Claims relied on this wording to rule that this provision does not **require** a finding of residual seizure disorder, **even if** its conditions are met. The Federal Circuit quite properly overruled this holding.



(2)(B). These modifiers are, to-wit: "(factors unrelated) ***does not*** include" and "(factors unrelated) ***may*** include."

Thus, speaking of "factors unrelated" for the **general** purposes of the two-step inquiry under Section 13, the statute says what factors unrelated are **not** ("does not include" . . . etc.), but it does not say completely what they **are**. They only **include** toxins, trauma, metabolic disturbance, and infection. Thus, they may arguably include genetic disorders, or "chronic organic brain syndrome." However, as in the case of any of these listed processes, it is impossible to prove actual causation without describing a mechanism for injury **at the specific time and place**. According to the actual causation case law, this is what must be shown. *See, e.g., Grant v. Secretary of DHHS*, 956 F.2d 1144 (Fed. Cir. 1992).

In contrast, the operative language in Section 14 shows that the **Table** Injury does **not** allow consideration of the open-ended definition of "factors unrelated." Instead, the language denotes **exactly** what it takes to rebut the presumption of vaccine-related causation. The language states that a condition either "***shall*** be considered a condition set forth on the Table," or that it "***shall not be*** considered a condition set forth on the Table." (Emphasis added). In this latter case, the showing to rebut the presumption is not open-ended:

> "If . . . an encephalopathy ***was caused by*** infections, toxins, trauma ***or*** metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table . . . " 42 U.S.C. § 300aa-14(b)(3)(B) (emphasis added).

The resolution of the ambiguity between permissive and mandatory language in the qualifications and aids to interpretation must be accomplished in a manner consistent with the overall purpose of the act. *See, Director Office of Worker's Compensation Programs, U.S. Department of Labor v. Perini North River Associates*, 459 U.S. 297, 103 S.Ct. 634, 74 L.Ed.2d 465 (1983). In the *Pereni* case, Justice Sandra Day O'Connor, writing for this Court, observed *inter alia* that it has been "long held" that the compensation statute is to be liberally construed, "in conformance with its purpose, and in a way which avoids harsh and incongruous results." *Id.*, 101 S.Ct. at 646.

> "***The system is intended*** to be expeditious and fair. It is also intended ***to compensate*** persons with recognized vaccine injuries ***without*** requiring the ***difficult individual determinations of causation*** . . . " H.R. 99-908, 99th Cong., 2nd Session, pt. 1, page 12, *reprinted* 6 USCCAN 6344, 6353 (1986) (emphasis added).

## II. THE GOVERNMENT CANNOT JUSTIFY A GRANT OF *CERTIORARI* AS A MATTER OF THE RESULT BELOW AND ITS IMPLICATIONS FOR OTHER CASES.

Perhaps the most absurd of all statements in the Petitioner's Brief is the discussion beginning at page 11 which asserts that **any** seizures in the Table time of three days would result in an irrebuttable presumption in favor of compensation. It is hard to conceive how a special master could make such a decision. The legislative intent makes the following statement, with which all the special masters are doubtless familiar:



> " * * * The Committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might be legitimately described as preexisting, (*e.g.*, a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (*e.g.*, a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intends that the time periods set forth in the Table apply to the significant aggravation . . . " House Rep. No. 99-908, 99th Cong., 2nd Sess. page 15, *reprinted*, 6 USCCAN 6344, 6356 (1986).

Moreover, the Court of Federal Claims has ruled in the case of children with Tuberous Sclerosis (a **potentially** but not necessarily devasating congenital disorder) that

> "The court need not tarry to conclude that a ***seemingly normal child*** who has never seized, but who suffers a latent pre-existing condition that is awakened by the vaccine also falls well within the intent of Congress to compensate under the Act." *Costa v. Secretary of DHHS*, 26 Cl. Ct. 866, 870 (1992) (emphasis added).

It would not be necessary, then, that this Court step in to prevent the type of scenario envisioned by the government as a result of the *Whitecotton* rule. It is proper that it be left standing to reinforce the essential nature of the Act:

> " * * * Congress has clearly and repeatedly indicated that it meant to provide compensation

even in those cases where there is a debatable causal link between the injury and the vaccine in question so as to ensure that those with meritorious claims would receive compensation. It was for this precise reason that Congress, in its wisdom, decided to permit recovery on a theory of presumed causation under the vaccine injury table, and has twice stated that it intended to create a system that provides compensation to persons with vaccine related injuries quickly, easily, and with certainty and generosity, and to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury." *McClendon v. Secretary of DHHS*, 24 Cl. Ct. 329, 334 (1991).

That Congress intended Maggie Whitecotton to receive compensation is reinforced by its specific statement of legislative intent:

> "The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information . . . Until such time, however, ***the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table*** and whose injuries cannot be demonstrated to be caused by other factors. (emphasis added) H.R. 99-908, page 18, *reprinted*, 6 USCCAN 6344, 6359 (1986).



Prior to *Whitecotton*, the government has regarded its burden in vaccine cases as merely to **identify** the existence of a factor unrelated. And the Office of Special Masters has been far too willing to go along.

The greatest frustration of the original purpose of the Vaccine Act has been its failure to bolster confidence in the Federal government's assumption of control over the immunization effort. The overly-broad application of "factors unrelated" is a prime source of this failure. The development of judicial doctrines that require the significantly-aggravated condition to be shown as a actual injury, **by petitioners**, is the engine of this untoward trend. But the statute as conceived and written should control.

## CONCLUSION

As stated before, the fiscal worries raised by the government are insubstantial. Just as an award under the Act would make the petitioner ineligible for Medicaid, the disability will only cost the taxpayers that amount of money one time, whether the benefits come from the Program[20] or from Medicaid and other agencies. And the

[20] The injustice to Maggie Whitecotton which would flow from a grant of *certiorari* are substantial. Benefits are not payable in the "retrospective" case until the date of judgment. Under 42

"prospective" injury trust fund will not run out of money. Most importantly, awards to such obviously vaccine-injured children bolster public confidence in the Program, which after all has the goal of promoting widespread immunization.

The government has completely failed to point out any substantial legal consideration as contemplated by Rule 10. There is no departure from the normal and accepted course of judicial proceedings. There is, as noted by the government (Petitioner's Brief, page 10), a consistency between the decision below and the Federal Circuit's previous decision in *Koston v. Secretary of DHHS*, 974 F.2d 157 (Fed. Cir. 1992). The matter does not present a Federal question which should be decided by this Court.

Moreover, the Program will work much more smoothly, if the government is forcefully repelled it its efforts to use the slightest excuse, the most hypothetical "factor unrelated," as a defense. Maggie Whitecotton's case was filed in 1990. The ferociously adversarial litigation has gone on too long, and consumed too many resources.

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U.S.C. § 300aa-15(a)(1)(A), the benefits are "(a)ctual unreimbursable expenses from the date of judgment awarding such expenses and reasonable projected unreimbursable expenses . . . "



*Whitecotton v. Secretary of DHHS* should stand, as the Federal Circuit precedent which finally makes the Vaccine Act work.

Respectfully submitted this 30th day of September, 1994.

Respectfully submitted,

Robert T. Moxley
Gage & Moxley
Attorneys at Law
623 West 20th Street
Post Office Box 1223
Cheyenne, Wyoming 82003-1223
Phone (307) 632-1112

No. 94-372

# In the Supreme Court of the United States

OCTOBER TERM, 1994

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DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

---

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

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## REPLY BRIEF FOR THE PETITIONER

---

DREW S. DAYS, III
*Solicitor General*
*Department of Justice*
*Washington, D.C. 20530*
*(202) 514-2217*

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1. We have argued in our petition (Pet. 12-15) that the court of appeals erred in holding that the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.*, creates a presumption that a vaccine has caused a compensable injury any time that a child with a pre-existing condition experiences an additional symptom or manifestation of that condition during the statutory period. The text of the Act unambiguously limits compensation in such circumstances to cases in which the child's preexisting condition was "significantly aggravated" during the statutory period, 42 U.S.C. 300aa-11(c)(1)(C)(i)—a showing that was not made here. See Pet. 8-9, 13.

Respondents offer no defense of the court of appeals' interpretation of the Vaccine Act. Instead, they seek to defend the judgment on another ground. Respondents assert (Br. in Opp. 12-19) that Maggie Whitecotton did not have clinically significant microcephaly before she took her third DPT vaccine, and that the seizures she suffered after the vaccination were therefore the first manifestations of her encephalopathy. That assertion ignores the special master's findings, which were affirmed by the Court of Federal Claims and were not disturbed by the court of appeals.

Based on the sources cited by the parties at the hearing on respondents' claim, as well as one additional source previously relied upon by the Court of Federal Claims, the special master adopted what he found "to be the most commonly accepted definition of microcephaly, namely, a head size smaller than two standard deviations below the mean for a child of the same sex and age." Pet. App. 32a. Applying that definition, the special master found that Maggie was "at least borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot on August 18, 1975." *Id.* at 32a-33a. The special master's finding was supported not only by evidence offered by the government, but also by respondents' own expert, who testified that "[s]omething was clearly happening to the child before [the DPT shot]." *Id.* at 33a. In his report, respondents' expert elaborated that the growth of Maggie's head had fallen below the normal curve, which "implie[d] a post-partum injury to the brain, at or near three months of age." *Id.* at 34a. The administration of the DPT vaccine that respondents allege as the cause of Maggie's condition occurred later, almost four months after she was born. *Id.* at 11a. In light of that evidence, the special master reasonably found that "[w]hether the



injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975." *Id.* at 34a.*

The court of appeals did not expressly affirm the special master's finding that Maggie was microcephalic before her third DPT vaccination. Pet. App. 8a. But neither did it disturb that finding. To the contrary, the court of appeals acknowledged that "[l]ogically, [the special master's findings] point to some preexisting condition, and not the vaccine, as the source of Maggie's injury." *Ibid.* The court of appeals held, however, that the special master's findings were irrelevant in deciding whether Maggie had suffered a Table encephalopathy. In the court's view, to benefit from the statutory presumption of causation, the claimant need only show that a symptom of an encephalopathy happened to occur during the Table period, not that the *first* such symptom occurred during that period. *Id.* at 5a. It is that legal holding we challenge in our petition.

The United States has not sought to deprive respondents of the opportunity to present arguments to the court of appeals on the factual issues of whether Maggie was clinically microcephalic before taking the vaccine and whether her preexisting condition was significantly aggravated during the Table period. What the United

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* In affirming the special master's finding, the Court of Federal Claims rejected respondents' contention that the special master had arbitrarily adopted the strictest definition of microcephaly. Pet. App. 20a. The court noted that "[e]ach of the experts that testified in this case acknowledged that this definition was accepted by the medical profession." *Ibid.* The court of appeals did not overturn that factual finding. Respondents' objection to that finding (Br. in Opp. 12-19) is without merit, and it does not in any event furnish a basis to deny review of the court of appeals' erroneous legal rulings.

States objects to is the court of appeals' conclusion that it is no longer necessary to resolve factual questions like that to decide whether a child is entitled to compensation. The court's holding that a child is presumptively entitled to compensation upon proof that a symptom or manifestation of a Table condition happened to occur within the Table period, without regard to whether the child was already suffering from such a condition, reflects a serious misinterpretation of the Vaccine Act.

2. As we have argued in the certiorari petition (Pet. 17-19), the court of appeals compounded its error by holding that the government could not rely on Maggie's microcephaly to rebut a prima facie case of causation. Pet. App. 7a-8a. The Vaccine Act permits the government to rely on "factors unrelated" to the vaccine to rebut a prima facie case. 42 U.S.C. 300aa-13(a)(1)(B). And while the statute precludes reliance on "idiopathic" factors, 42 U.S.C. 300aa-13(a)(2)(A), Maggie's microcephaly is not idiopathic, since it is a defined preexisting condition that logically eliminates the vaccine as the cause of her condition. See Pet. 17-19.

Rather than defending the court of appeals' reasoning, respondents offer an even more restrictive view of what constitutes a permissible rebuttal of a prima facie case. Respondents contend (Br. in Opp. 19) that "factors unrelated" to the vaccine are limited to "toxins, trauma, infection or metabolic disturbance." Since Maggie's microcephaly cannot be traced to one of those four factors, respondents argue, the government failed to establish that a factor unrelated to the vaccine caused Maggie's condition. Respondents' contention is without merit.

Section 300aa-13(a)(2)(B) provides that factors unrelated to the vaccine "may * * * include infection,



toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." 42 U.S.C. 300aa-13(a)(2)(B). The words "may include" indicate that Congress intended that the four identified factors be treated as examples of permissible rebuttal, rather than as an exhaustive list.

Respondents appear to concede that point, but then contend (Br. in Opp. 21-22) that the permissive language of that provision is overridden by Section 300aa-14(b)(3)(B), which relates to encephalopathies. That section provides that "[i]f * * * an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table." 42 U.S.C. 300aa-14(b)(3)(B). That language, however, simply mirrors the text of Section 300aa-13(a)(2)(B). Nothing in that language compels the conclusion that the four listed factors were intended to be the only factors that could defeat a finding of a Table encephalopathy.

Respondents argue (Br. in Opp. 20-21) that the use of the word "shall" suggests that the four factors are exclusive rather than illustrative. But the term "shall" simply indicates that if the government proves that one of the four listed factors caused the child's injury, the court must deny compensation. It does not suggest that if the government proves that a different factor caused the encephalopathy, the court must ignore the force of that evidence. Moreover, the second sentence of Section 300aa-14(b)(3)(B) confirms that the first sentence was not intended to limit rebuttal to the four identified factors. The second sentence provides that "[i]f at the

time a judgment is entered * * * it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table." If respondents' construction of the first sentence were correct, the second sentence would have provided that "if an encephalopathy is not shown by a preponderance of the evidence to have been caused by infection, toxins, trauma, or metabolic disturbances, the encephalopathy shall be considered to be a condition set forth in the table." The quite different and more limited scope of the second sentence makes clear that the government can rely on a factor that is not one of the listed four, as long as it is possible to determine by a preponderance of the evidence that the factor identified by the government caused the encephalopathy.

Respondents' more restrictive interpretation makes no sense. If respondents' view were accepted, it would mean that, for no apparent reason, Congress adopted a different standard of rebuttal for encephalopathies than for all other Table conditions. Even more significantly, it would mean that in cases involving encephalopathies, the Secretary would be unable to rely on genetic conditions, such as Down's syndrome, to rebut a prima facie case. Congress could not have intended that result.

3. Finally, respondents erroneously contend (Br. in Opp. 11) that our concerns about the financial implications of the court of appeals' decision are artificial. As we have explained (Pet. 19-20), the court of appeals' decision, if allowed to stand, would immediately threaten the fiscal integrity of the fund for retrospective cases and could readily require $200 million in additional (and erroneous) compensation awards over the next ten years.



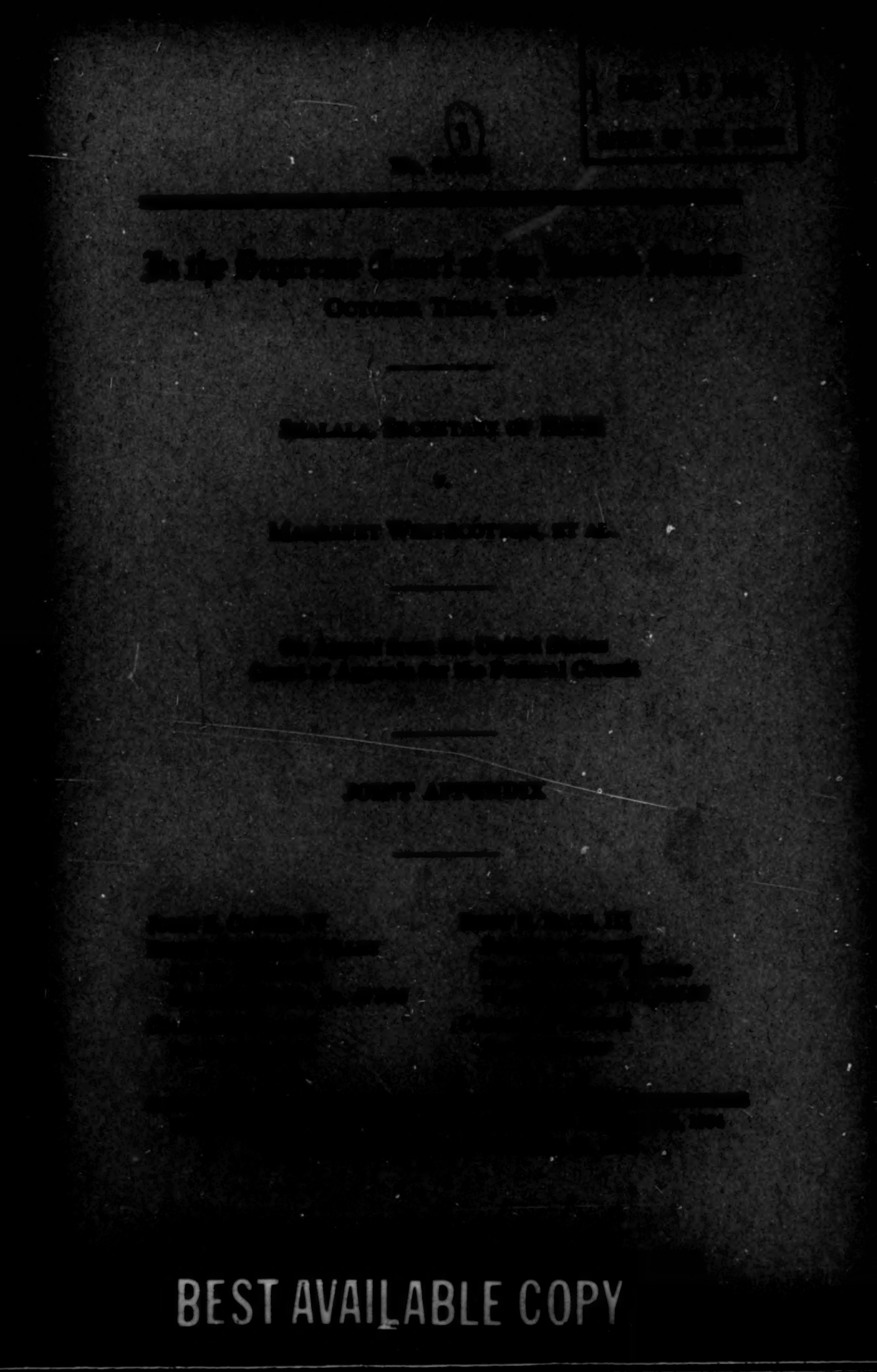
## CONCLUSION

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

DREW S. DAYS, III
*Solicitor General*

OCTOBER 1994



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UNITED STATES FEDERAL COURT
OF FEDERAL CLAIMS

Civil Docket for Case #: 90-VV-692

MARGARET WHITECOTTON, ET AL., PLAINTIFF

*v.*

DONNA E. SHALALA, SECRETARY OF H&HS,
DEFENDANT

**DOCKET ENTRIES**

| DATE | PROCEEDINGS |
|---|---|
| Jul 24 1990 | Filing fee of $120 paid by petitioners. |
| Jul 24 1990 | Notice of assignment to Special Master Paul Baird filed. Copy to parties. |
| Jul 31 1990 | Respondent's notice of appearance filed. Service: 7/30/90. |
| Aug 1 1990 | Petitioners' notice of filing Exhibit J, contained in three binders, filed. Service: 7/31/90. |
| Aug 2 1990 | Special Master's notice to parties re proceedings filed. Copy to parties. |
| Oct 1 1990 | Petitioners' notice of filing document (Exhibit K) filed. Service: 10/9/90. |
| Oct 22 1990 | Respondent's notice of appearance filed. Service: 10/19/90. |
| Oct 22 1990 | Special Master's order suspending proceedings for 30 days; and directing respondent to file report by November 21, 1990 filed. Copy to parties. |

| DATE | PROCEEDINGS |
|---|---|
| Nov 21 1990 | Special Master's order entered suspending proceedings for 30 days, with respondent's report due DEC 21 1990. Copy to parties. |
| Dec 21 1990 | Respondent's report filed. Service: 12/21/90. |
| Jan 7 1991 | Order scheduling status conference; further proceedings; and directing parties to file one copy with original documents filed. Copy to parties. |
| Jan 23 1991 | Special Master's order entered scheduling a status conference and a hearing re entitlement. Copy to parties. |
| Feb 6 1991 | Respondent's notice of filing (Exhibit B, curriculum vitae) filed. Service: 2/5/91. |
| Feb 11 1991 | Order entered suspending proceedings for 60 days, and vacating April 4 hearing date. Copy to parties. |
| Apr 18 1991 | Order scheduling hearing; scheduling prehearing conference; each party to file prehearing memorandum, witness list, and exhibit list by May 21, 1991 filed. Copy to parties. |
| May 21 1991 | Respondent's pre-hearing memorandum, witness and exhibit list filed. Service: 5/21/91. |
| May 28 1991 | Special Master's order entered rescheduling prehearing conference. Copy to parties. |
| May 31 1991 | Petitioner's prehearing memorandum, witness and exhibit list with (exhibits L-N) filed. Service: 5/30/91. |
| Jun 10 1991 | Petitioner's exhibits 53 through 56 filed. Service: 6/7/91. |
| June 18 1991 | Petitioner's exhibits Q, R, S, T, & U filed. Service: 5/14/91. |



| DATE | PROCEEDINGS |
|---|---|
| June 19 1991 | Transcript of proceedings (1 volume) taken at Indianapolis, Indiana, on June 4, 1991; together with petitioner's exhibits 0-1 through 0-9 and 1 and 2 filed. Notice to parties. |
| Jul 3 1991 | Petitioner's affidavit of John S. Capper IV filed. Service: 7/2/91. |
| Jul 3 1991 | Petitioner's exhibit V filed. Service: 7/1/91. |
| Jul 17 1991 | Order that respondent file written source of authority in 7 days; petitioners may respond 10 days from filing; and suspending proceedings for 30 days filed. Copy to parties. |
| Jul 24 1991 | Respondent's notice of filing exhibits 57-59 filed. Service: 7/23/91. |
| Aug 13 1991 | Petitioner's notice of filing exhibit W filed. Service: 8/12/91. |
| Aug 16 1991 | Special Master's decision filed. Copy to parties with petitioner served via Fed Ex. |
| Sep 16 1991 | Petitioner's motion for review of the special master's decision filed. Service: 9/13/91, Judge and SM. |
| Sep 16 1991 | Notice of assignment to Judge James T. Turner filed. Copy to parties, Judge and SM. |
| Oct 16 1991 | Respondent's response to motion for review filed. Service: 10/16/91 SM and Judge. |
| Jan 14 1992 | Judge's opinion and order overruling petitioner's objections to special master's decision; and directing Clerk to enter judgment for respondent in accordance to special master's 8/16/91 decision filed. Copy to parties with petitioner served via Fed Ex. Copy to SM. |

| DATE | PROCEEDINGS |
|---|---|
| Jan 29 1992 | Judgment entered that the petition is dismissed. Copy to parties. Judge & SM. |
| Mar 30 1992 | Petitioner's motion to set aside judgment and for rehearing filed pursuant to Rule 60(b). Service: 3/27/92. Copy to SM. |
| Apr 1 1992 | Notice of filing petition for review in the CAFC on March 27, 1992, received. C.A.F.C. #92-5083. Copy to Judge and SM. |
| Apr 13 1992 | Respondent's brief in response to petitioners' motion to set aside judgment and for rehearing filed. Service: 4/13/92. |
| Jun 2 1992 | Respondent's notice of appearance filed. Service: 6/2/92. |
| Jun 26 1992 | Order from the CAFC entered staying proceedings pending ruling on Claims Court ruling on its 60(b) motion etc. Copy to parties. Judge and SM. |
| Jul 1 1992 | Judge's order of remand to the Special Master filed. Copy to parties and to SM. |
| Aug 25 1992 | Petitioner's amended Table of Contents filed by leave of the Judge. |
| Aug 25 1992 | Petitioner's verified motion for leave to file amended and supplemental motion under Rules 59 and 60(b); motion for procedural ruling and for evidentiary hearing; etc. filed by leave of the Judge. Service: 8/21/92. SEE ORDER ENTERED AUG 25 1992. |
| Aug 25 1992 | Order entered granting petitioner's motion for leave to file amended and supplemental motion under Rules 59 and 60(b), etc., with respondent afforded 14 days from the date of filing to respond. Copy to parties. |



| DATE | PROCEEDINGS |
|---|---|
| Aug 25 1992 | Petitioner's amended and supplemental motion under Rules 59 and 60(b); motion for procedural ruling and for evidentiary hearing; etc. filed. SEE ORDER ENTERED AUG 25 1992. |
| Aug 25 1992 | Respondent's response to petitioner's amended motion under RUSCC 60(b) filed. Service: 8/17/92. |
| Aug 25 1992 | Judge's order entered denying petitioner's motion to reverse the remand or for relief from judgment, and confirming in all respects the order of remand entered July 1, 1992. Copy to parties and to SM. |
| Sep 15 1992 | Order entered denying petitioner's motion for leave to file amended and supplemental motion under Rules 59 and 60(b), etc. Copy to parties and to Judge. |
| Oct 15 1992 | Petitioners' motion for review, and in the alternative, for order rejecting special master's "report" on Rule 60(b) proceedings filed. Service: 10/14/92. |
| Oct 15 1992 | Petitioners' motion for leave to file overlength memorandum of objections in support of motion for review, etc. filed. Service: 10/14/92. GRANTED BY ORDER ENTERED OCT 20 1992. Copy to parties. |
| Oct 20 1992 | Petitioner's overlength memorandum of objections in support of motion for review filed. |
| Nov 16 1992 | Respondent's response to petitioners' motion for review filed. Service: 11/16/92. |
| Jan 7 1993 | Judge's opinion and order entered denying petitioner's motion for relief from judgment pursuant to RCFC 60(b)(2). Copy to parties and to SM. |

| DATE | PROCEEDINGS |
|---|---|
| Jan 12 1993 | Judgment entered that the petition is dismissed. Copy to parties. |
| Feb 4 1993 | Corrected judgment entered that petitioners' motion to vacate the judgment of 1/29/92 is denied. Copy to parties Judge and SM. |
| Mar 18 1993 | Notice of filing petition for review by petitioner's, CAFC #93-5101 received. Copy to Special Master and Judge. |



U.S. DISTRICT COURT
UNITED STATES COURT OF FEDERAL CLAIMS
(U.S.C.F.C.)

Civil Docket for Case #: 90-VV-692

WHITECOTTON, ET AL.

v.

HHS

**DOCKET ENTRIES**

| DATE | Nr. | PROCEEDINGS |
|---|---|---|
| 7/24/90 | 1 | PETITION by MARGARET WHITECOTTON, KAY WHITECOTTON, MICHAEL WHITECOTTON FILING FEE $120 Vac. Date: 08/18/75 (pf) [Entry date 03/16/94] |
| 7/24/90 | — | CASE assigned to Judge Unassigned. (pf) [Entry date 03/16/94] |
| 7/24/90 | 2 | NOTICE OF assigned to Special Master Paul Baird. Copy to parties. (pf) [Entry date 03/16/94] |
| 9/16/91 | 3 | Notice of assignment to Judge James T. Turner. Copy to parties. (pf) [Entry date 03/16/94] |
| 1/14/92 | 4 | UNPUBLISHED DECISION entered overruling petitioner's objections to Special Master's August 16, 1991 decision, and Dismissing the petition (signed by Judge James T. Turner). Copy to parties. (tw) [Entry date 05/04/94] |

| DATE | Nr. | PROCEEDINGS |
|---|---|---|
| 1/29/92 | 6 | JUDGMENT entered that the petition is dismissed. (signed by Clerk). Copy to parties, Judge, and Special Master. (bh) [Entry date 03/23/94] |
| 1/29/92 | — | Case closed. (bh) [Entry date 03/23/94] |
| 3/18/93 | 8 | NOTICE FROM CAFC re: filing of Petition for Review by MARGARET WHITECOTTON, KAY WHITECOTTON, MICHAEL WHITECOTTON CAFC #93-5101 received. (hw) [Entry date 09/07/94] |
| 3/15/94 | 4 | See case No. 90-551v for notice to parties re: resignation of Special Master Baird (pf) [Entry date 03/16/94] |
| 5/6/94 | 5 | MANDATE (certified copy) of the CAFC dated May 6, 1994, reversing and remanding the [7-1] petition for review filed by Margaret Whitecotton, Kay Whitecotton, and Michael Whitecotton (Vacate judgment deadline on 6/6/94). (hw) [Entry date 05/11/94] |
| 5/6/94 | 7 | MOTION by MARGARET WHITECOTTON, KAY WHITECOTTON, MICHAEL WHITECOTTON (Service:) For review of Special Master's Decision Judge James T. Turner (Judge's decision due on 9/6/94) Response due: 6/6/94 (rs) [Entry date 08/31/94] |
| 5/11/94 | 6 | ORDER entered Vacating [6-1] judgment order and remanding the case to Office of Special Master (signed by Judge James T. Turner). Copy to parties. (hw) [Entry date 05/12/94] |
| 5/11/94 | — | Case reopened. (hw) [Entry date 05/12/94] |



| DATE | Nr. | PROCEEDINGS |
|---|---|---|
| 5/11/94 | 7 | ORDER entered Vacating [6-1] judgment order, and remanding case to Special Master's for a determination of compensation pursuant to said opinion and mandate of the Federal Circuit Court of Appeals (signed by Judge James T. Turner). Copy to parties. (hw) [Entry date 05/20/94] |
| 7/18/94 | 8 | ORDER set Life Care Plan due: 9/12/94 for MICHAEL WHITECOTTON, et al. and directing Respondent to evaluate and contact court with two agreed upon dates for status conference no later than October 24, 1994 (signed by Chief Special Master Gary J. Golkiewicz). Copy to parties. (as) [Entry date 07/26/94] |
| 9/12/94 | 9 | MOTION by MARGARET WHITECOTTON (Service: 9/9/94) to Extend Time to file its life care plan [60 days]. Response due: 9/26/94 (as) [Entry date 09/13/94] |
| 10/5/94 | 10 | ORDER granting [9-1] motion to Extend Time to file its life care plan and reset Life Care Plan due: 11/14/94 for MICHAEL WHITECOTTON (signed by Chief Special Master Gary J. Golkiewicz). Copy to parties. (as) [Entry date 10/13/94] |
| 11/28/94 | 11 | MOTION by MARGARET WHITECOTTON, KAY WHITECOTTON, MICHAEL WHITECOTTON (Service: 11/21/94) to Stay of the deadline to file the life care plan (to 60 days). Response due: 12/8/94 (mp) [Entry date 11/30/94] |

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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92-5083, 93-5101

MARGARET WHITECOTTON, by her next friends,
KAY WHITECOTTON and MICHAEL WHITECOTTON,
PETITIONERS-APPELLANTS

*v.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
RESPONDENT-APPELLEE

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JUDGMENT

On appeal from the United States Court of Federal Claims in Case No(s). 90-692V,

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

REVERSED AND REMANDED

ENTERED BY ORDER OF THE COURT

/s/ Francis X. Gindhart
FRANCIS X. GINDHART
Clerk

Dated Feb. 15, 1994

ISSUED AS A MANDATE: May 6, 1994



STATE OF WEST VIRGINIA )
) ss:
COUNTY OF MAIDALL )

**AFFIDAVIT**

I, Ellen L. Kitts, M.D., after being duly sworn upon my oath, state the following:

Margaret (Maggie) Whitecotton was born April 22, 1975, following a normal prenatal course, normal labor, normal delivery. Apgars were 8 and 9. She was seen by her family physician, Dr. Shannon, at age three weeks, six weeks, two months, three months. All examinations were normal and she was deemed to be a normal child. On August 18, 1975, she received her third DPT injection and second oral polio vaccine. Her temperature (rectal) at the time of injection was 99.8-100 degrees. She developed a dime sized area of induration at the sight of the injection. On August 19, one day following her third DPT and second oral polio, Maggie developed clonic seizures with symmetrical limb jerking of the upper extremities. She stopped sucking and the pacifier dropped from her mouth. Her head tilted back. It was within twenty-four hours of that injection, following this her development slowed. The speed of growth of her head size slowed and fell off the growth curve. For all of the above reasons Maggie has post vaccine encephalopathy that presented with seizures twenty-four hours after the vaccination. Her encephalopathy has resulted in cerebral palsy, mental retardation, seizures, and she is non-verbal.

The diagnosis of post vaccine seizures and encephalopathy is confirmed by: the change in rate of head growth which slowed following the third vaccination, by reports by Dr. Keith Baird, and by the Marion County General Hospital discharge summary dictated by Stanley Wissman, M.D. It is important to note that on 3/24/80 she was admitted to the hospital with seizures following a DT im-

munization given the day before. She was well prior to the immunization. This indicates that the reaction may have been to the diptheria and/or the tetanus rather than the pertussis. But again a definite correlation exists between the vaccination and the seizures. There is no other causation for her condition.

I am able to report that generally Maggie is a very happy child. However, she has had significant pain and suffering as a result of her difficulties. She required surgery for a dislocated hip. This resulted in at least six weeks of being in a total body cast. Following the surgery she lost her ability to walk and this has not been regained.

Unfortunately the surgery was not successful. Another operation is being planned. Again there is significant amounts of pain often requiring narcotic pain medication during the first few days post operatively. She will again be required to wear a body cast for six to eight weeks. During which time she has no mobility. She is bed fast. She cannot attend school.

Maggie recently underwent a two stage spinal operation. This resulted in a several day stay in the intensive care unit. Following the initial surgery she was unable to sit up. There was considerable emotional suffering in that we were unable to explain the surgery, its reasons, or why she was hurting or how soon she would be better. Approximately two weeks later she underwent a second stage spinal operation. Again this resulted in a new onset of acute surgical pain. Within a reasonable degree of medical certainty Maggie will develop arthritis in the hip that has required the surgery. This will occur in early adult life (age 30 or 40, compared to age 50 or 60). This will then be present the rest of her life.

Based on Maggie's low intellect I doubt that she could separate out emotional stress from pain and suffering.

Maggie has cerebral palsy. She has already required one inpatient rehabilitation stay in an effort to better define her problems and help the family put together an



appropriate management strategy. At present she is receiving an appropriate outpatient program. It is my hope that at most she will require two other rehabilitation stays. The first will be to help her regain her ambulatory skills following her hip surgery. I would anticipate this stay lasting four to six weeks. A second rehabilitation stay may be required at the end of her education to help put together an appropriate prevocational/vocational program. It would look at her skills, her needs for specialized adaptive equipment and then would assist with job placement in a sheltered workshop. This would be done at a vocational rehab center. Maggie does require developmental evaluations and intellectual evaluations on an ongoing basis. With her placement in a special education setting IQ tests and psychological tests must be done every two years. In addition she did undergo a rehabilitation admission specifically for a developmental evaluation. At Maggie's age, these evaluations are done by an occupational therapy, physical therapy, speech and language therapy, an educator, and eventually a vocational rehabilitation specialist.

Maggie will require special education throughout her school years. She currently is functioning in a trainable mentally retarded setting. This will be ongoing until she reaches adult life. The problems are compounded by the fact that she is non-verbal. Thus it is even more difficult for those around her to know what she knows and understands. Much time and effort is being spent trying to create a communication system for her. Because she is non-verbal this makes vocational training and placement even more difficult.

Vocational training and placement outside a sheltered workshop is probably impossible. Maggie's low IQ significantly limits her job opportunities. This is compounded by the fact that she is non-verbal and therefore cannot ask questions, talk to other staff or clients, or make her ideas, wants or needs known. Her physical limitations will also be a significant factor. At present she is independently mobile in a manual wheelchair.

It is hoped that in time she will again become ambulatory but this is unknown. Her fine motor skills are somewhat slow and delayed and she is uncoordinated. As a result I feel the most advanced possible placement would be a sheltered workshop and this may be very difficult to find for her.

Based on my current assessment, Maggie will always require one to one supervision. She has a very short attention span and would not be able to stay on task. She needs constant twenty-four hour monitoring for seizures so that if one develops she can receive the appropriate help. This twenty-four hour attendant care would need to be performed by an appropriate attendant who is qualified to monitor seizures, give medication and respond approriately when a seizure occurs. In addition to this she needs one to one assistance for mobility, toileting, activities of daily living, etc. She will never be able to manage her own finances.

Any case as complex as Maggie does require a case manager. This person would help the family find appropriate therapists. They would help the family obtain and monitor appropriate one to one caregivers. They would help to coordinate all of her services. In addition to this they would help the family with coordination of all Maggie's bills. Case managers are frequently social service personnel, although at other times they are people who have worked in the insurance business or in medical rehab services.

Based on Maggie's low IQ, I doubt that she will ever need psychological counseling. However, her family, parents, and/or her siblings may well benefit from this at different points in their lives to help them adjust to Maggie and her disabilities. Counseling may also be necessary to help them adjust to the changes in their lives that are the result of Maggie's disability. As her parents get older Maggie's brother may need counseling and support as he decides the role that he will play in Maggie's life and her care.



Maggie currently is involved in a behavioral management program. At present this is being done through the school. However, in a sheltered workshop, group home environment, or in the home setting she may develop other behaviors that need to be modified or changed. If the family's routine measures are unsuccessful the specialist in behavior management will be consulted. Such specialists are usually psychologists. She would require intervention on a weekly basis for several months until the behaviors came under control.

It is in my recommendation to any family that at some point all children need to leave home. This certainly occurs at different ages and under different circumstances based on the family, the children and the disabilities the children exhibit. In leaving home the best possible option for Maggie would be a group home setting. These usually provide the lease restrictive environment compared to an extended care facility. Group homes work very hard to provide the clients with a day program that often is a sheltered workshop or job oriented. In the evenings the client's time is filled with routine housekeeping tasks, recreational activities, activities of daily living, interaction with relatives and peers. In each of these settings, Maggie will continue to need her own independent one-to-one care attendant.

If the family chooses to continue to have Maggie living in their home the extra support staff become even more important. Once Maggie reaches an appropriate age she needs independence from her parents and they need independence from their children. In order to maintain Maggie in their home this means that Maggie would still require twenty-four hour one-to-one attendant care as mentioned hereinabove. In this sort of a supervised setting the family could have their independence. Likewise Maggie too could be independent. It would increase Maggie's recreational activities, increase reinforcement of her educational setting and two people will be needed to assist her with her activities of daily living, transfers,

hygiene, etc. By living at home the family has to remain active in supervision the care takers, planning or supervising the care programs, making arrangements for the recreational activities and coordinating staff work schedules.

Maggie does require special equipment. At present she is non-ambulatory. As a result she needs an ultralightweight wheelchair with removal desk arms, swing away removable foot rests, heel loops, brake extensions, seat belt. Maggie also requires grab bars for the bath tub. If her final hip surgery is not successful she'll need help transferring in and out of the bathtub. This would be in the form of a hydraulic lift, a shower that is either wheelchair accessible or has a shower bench so that she can transfer laterally and shower in the sitting position would be the other alternative. Were the family ever to go on vacation and choose not to take Maggie with them she would then require round the clock care for management and supervision. She may need two people at times to help with dressing, hygiene, etc.

The residence does need to be wheelchair accessible. This means that areas need to be ramped. Hallways, doorways, etc., need to be extra wide. If Maggie is again to become ambulatory she will require a rolator walker. She may well require a Kaye posture control walker. Grab rails along the length of hallways may be necessary to provide support while walking.

Maggie does require exercise equipment that is enjoyable for her. Outdoor playground equipment such as swings would need to be modified to have a back as well as a seat. They should also have a seat belt. She will require an adult sized tricycle and/or bicycle with large training wheels to provide another means of independent mobility. Maggie is currently working on a communications system. At present this is a communication board. As she becomes more successful she may need a communication device that has synthesized speech. Such a device should be chosen that could interface with



a computer which would allow for increased recreational activities, increased educational activities, and synthesized speech. Maggie requires hydrotherapy in a heated pool. This is highly motivating for her. It increases strength, increases coordination, increases cardiovascular condition. The water must be heated to decrease her tone and relax her muscles. It is needed to assist with her range of motion program. It will be used post operatively to help her regain her ambulation. Because of the Indiana climate it must be a heated indoor pool.

Because of Maggie's cerebral palsy she should be seen by an orthopedist a minimum of every six months. She does need to be followed by a neurologist at least every six months to once a year. She needs to be seen by a family doctor and/or pediatrician a minimum of every six months to a year plus much more frequently whenever she would develop an illness. Although there have not been pediatric physiatrists in the area she would definitely benefit by seeing one again on an every six months basis. At present the closest people would be Chicago, Illinois, Columbus, Ohio, or Wheeling, W. Virginia. Because there are no specialists in Crawfordsville Maggie and her family have to travel a minimum of forty to fifty miles to have these appointments. This results in increased expenses for travel as well as increased phone bills.

In addition to this Maggie does need the chance to have time to be with her peers. She's an excellent candidate for Cerebral Palsy Camp, Sports by Ability Games, Special Olympics. Since it is very difficult for her to participate in many physical activities she requires social activities such as trips to the zoo or a Children's Museum. These activities need to have lots of visual stimuli, lots of activity, be very appealing to sight, sound and smell. There will always need to be tv as well as a VCR for entertainment.

I have seen Maggie Whitecotton during her inpatient rehabilitation stay at D.T. Watson Hospital, in the Meth-

odist Hospital rehabilitation clinic, and for two outpatient evaluations, one done in Indianapolis and the other done in Crawfordsville.

Maggie does have a normal adult life expectancy. Her seizures and cerebral palsy would not change her life expectancy in any way.

From a medical perspective Maggie has spastic quadriplegic cerebral palsy. The spasticity that came from the cerebral palsy has been enough to cause dislocation of her hip. The original surgery was not successful and the hip remains out. Following hip surgery the leg shortens. She may require surgery on the opposite leg to shorten it to develop and get a more equal leg length. If that is not necessary she will require special shoe lifts. If the lift is large enough it has to be attached to an ankle foot orthoses (brace) because the shoe itself cannot support the extra weight of the lift. Prior to the surgery Maggie was ambulatory. This skill has been lost. Now that her spinal surgery is complete we are in the process of getting appropriate orthopedic evaluations so that the surgical correction of her hip problem can be attempted again. Following hip surgery she will then require intensive rehabilitation treatment to help her regain ambulation. One more attempt needs to be made to put the hip back in the socket. If the hip is to remain out of the socket she will definitely develop early arthritis. This arthritis is made worse by the spasticity which chronically irritates the dislocated hip. It is very important to do this because she was ambulatory.

Because of the stiffness and spasticity, Maggie was never able to sit and fully extend her spine. She became contracted and eventually developed very severe kyphosis. This kyphosis causes a rounding of her spine such that it becomes impossible to look up. She is always looking at the floor. Were it not corrected she would lose her ability to sit. She would lose her ability to walk. She would not even be able to lie comfortably in bed because her spine would always be curved. This required two



different surgeries to correct. Without this surgery her back would have continued to curve. I'm happy to report that she has had an excellent surgical correction and is now doing well in her recovery phase.

We've talked about Maggie's limited intellect. At present she is functioning at about the equivalent of a two year old. This means that as an adult she will be functioning at the two and one-half to the three year old level. As a result she will always require adult supervision for care and for safety. She will never be financially self-sustaining. She will never be able to manage her own monies. A sheltered workshop will give her a sense of accomplishment and self-worth and help her contribute to society.

It is my hope that once her hip surgeries are completed that these will be the last surgeries that are necessary. Since she has reached her adult size she should not require other musculoskeletal surgeries.

Based on Maggie's age, she can now receive her rehabilitation in an adult setting although due to her intellect she may still do better in a pediatric setting. She would then require rehabilitation at the Rehabilitation Institute in Chicago, or in such centers as D.T. Watson, in Sewickey, Pennsylvania.

Since we don't know the final outcome of Maggie's hip surgery and her ambulatory abilities. There are still many unanswered questions about the overall amount of adaptive equipment she will require. She will never be able to drive a car. It is my hope that she will always be able to independently transfer from her wheelchair to a car. However, someone else would have to put the chair in the car for her. If these transfers become impossible she will then require a van. Since she will be an adult the van will need a lift. It would be best for her to remain seated in the chair. She would therefore need wheelchair locks and tie downs. This obviously then requires a larger garage.

Maggie's therapists could make a home visit to look closely at accessibility. If the plan is for Maggie to remain home throughout her adult life, she would need "an apartment" setting separate from the family, whether such an area can be created within the current home or whether an addition would need to be created could also be assessed.

Equipment such as wheelchairs are estimated to last approximately three years. Likewise at Maggie's age, I would estimate braces to last about three to five years.

Dated this 29th day of June, 1990.

/s/ Ellen L. Kitts MD
ELLEN L. KITTS, M.D.

[Notary Omitted in Printing]



[Dec. 3, 1990]

Vaccine Injury Compensation Program

Patient Claim CT. 90692

Patients Name: Whitecotton, Margaret A.

Case History:

This infant was born on 4/22/75 to a 29 year old gravida 1, mother whose pregnancy was described as normal. Delivery was uneventful with the exception of possible placenta accreta because of the need for manual extraction of the placenta and uterine bleeding. She had Apgars of 8 and 9 and the only significant physical finding at birth was a head circumference of 12½ inches which is below the third percentile. PKU screening test was normal and the hospital course was uneventful and she was discharged after three days.

The subsequent course up until four months of age was unremarkable with the exception of the infant's growth. There are meticulous records of growth measurements from birth onwards. The head circumference was recorded at three weeks, two months, three months, and four months of age and revealed head sizes of 33.5, 35.5, 36.5, and 37 cm. respectively. These are all below the 3rd percentile, and in fact, show a trend of falling off the curve from birth. Subsequent head measurements after four months of age continued the trend throughout childhood. Similarly the birth weight which started at the 10th percentile dropped to almost the 3rd percentile at four months and subsequently was below the 3rd percentile. The length began following off the growth curve at approximately 6 months.

At approximately four months of age the child was given the third DPT immunization and the second oral polio vaccine. Later that same day the mother noted the onset of twitching in the arms. A temperature was reported to

be approximately 100 degrees rectally. The child had three more episodes of arm twitching and at one point was associated with eye blinking. She was taken to the emergency room in Crawfordsville where the examination was reported normal, although the records of that evaluation, in that emergency room, are not available. She was seen the following day by Dr. Baird who observed similar activity. He described a seizure as clonic, fine jerking of the upper extremities that was symmetrical. He stated that the child stopped sucking during this episode and [her] head tilted back slightly. He did not describe the duration of the episode. A possible seizure was observed during the physical examination of the lower extremity. A lumbar puncture was normal although there is a report of possible abnormalities in the immunoglobulins of the CSF. An EEG showed some slowing and disorganization of the background. A brain scan was considered although there was no report of it having been done. No further seizures were observed and the child was discharged on no anticonvulsant medication.

She was admitted in February, 1976, at 10 months of age for a possible seizure disorder; however, the final diagnosis suggested acute airway obstruction. It was noted during that time that the child was hypertonic, microcephalic, and had failure to thrive. The child had several episodes of vomiting. Her examination showed spasticity and the family history of epilepsy in the father was documented. Laboratory evaluation, including TORCH titers and a lumbar puncture were unremarkable. Routine laboratory was unremarkable with the exception of persistent low serum bicarbonate on three different occasions with an elevated anion gap between 16 and 22 mEq/liter. This was not further evaluated.

She subsequently was followed at the Miriam County Cerebral Palsy Clinic where a diagnosis of spastic diplegia was repeatedly mentioned as well as microcephaly. Further, it was determined that she had congenital hip dislocation during these visits.



She was admitted at 20 months of age with a febrile illness and a generalized seizure with the only significant laboratory findings being a CSF pleocytosis of 43 cells which was not explained. She had no apparent infection at that time. She was hospitalized again in 1979 for possible seizures and it was noted that she had had swallowing difficulties since birth. She was hospitalized in October, 1979 for an orthopedic procedure for her hip.

At age 4½ she was given diphtheria and tetanus immunizations, and oral polio by mouth. She was doing well until the following morning when she suddenly developed a seizure and was described as having slight shaking movements in the arms and feet. She was given intramuscular Phenobarbital and intravenous Valium at the Culbert Union Hospital Emergency room at which time she improved. At the time of the emergency room visit her temperature was 102 and it was also noted that the brother had a similar febrile illness at home.

Her subsequent course was characteristic of children with cerebral palsy and mental retardation as documented by several psychometric tests and numerous orthopedic procedures.

The parents' affidavit was reviewed which stated that she developed the above described seizures after her third DPT and second OT immunization and that following this the speed of her head growth slowed, as well as her development. It was alleged that she exhibited post-vaccine encephalopathy resulting in cerebral palsy, mental retardation, and seizures.

Discussion: This 15 year old child has a chronic organic brain syndrome characterized by cerebral palsy, mental retardation, and seizures. In addition, there is a history of congenital hip dislocation, and feeding difficulties from

birth. There is a temporal association with the onset of the first observed seizure following shortly after the third DPT immunization and second oral polio vaccine administration. It is clear from the records that the onset of her microcephaly was at birth and there is no evidence from the records that this was accelerated by or related to the immunization.

As for the legal question of whether this child had a post-immunization encephalopathy, there is no clinical evidence to support an encephalopathy following the immunization such as altered consciousnes, focal or diffuse neurologic signs, or other impairment of brain function aside from the brief seizures that were observed. The abnormal disorganization and slowing of the EEG could possibly support a diagnosis of encephalopathy; however, in the clinical picture of co-existing seizures this is not diagnostic. Furthermore, there are no control studies that have shown an association between immunizations and progressive or chronic neurologic disease.

According to guidelines a residual seizure disorder can be diagnosed if the onset was noted within three days of the immunization and that there were at least two more seizures unaccompanied by a fever greater than 102 degrees within one year. There is no evidence from the record that this child had further seizures during this period.

It is my impression that this child's chronic organic brain syndrome is congenital in nature and not related to immunizations.

/s/ Owen B. Evans
OWEN B. EVANS, M.D.

OBE:jc



CHILDREN'S HEALTH CENTER

410 20th Street, Suite 104
Glenwood Springs, Colorado 81601
Telephone: 945-2571

August 8, 1991

Mr. John Capper
Attorney At Law
c/o Berry, Capper, & Tulley
131 North Green Street
P.O. Box 429
Crawfordsville, Indiana 47933

Re: Margaret Whitecotton
D.O.B.: 4/22/75

Dear Mr. Capper:

At your request I am writing this addenda to my report and testimony, in order to clarify the clinical use and medical definition of the term "microcephaly." I understand that Special Master Baird has requested this additional clarification.

In formulating this response I reviewed the letter of July 23, 1991, which Dr. Owens submitted to Ms. Hidalgo. This matter seems to be boiling down to two core questions: 1) Did Margaret Whitecotton have true microcephaly from birth? 2) If she did have true microcephaly, did that condition predispose her to seizures and profound mental retardation?

In several respects, I find myself in agreement with Dr. Owens' letter of July 23. We both agree on the authoritative nature of Nelson's *Textbook of Pediatrics (13th Edition)*. I also agree with his statistical explanation of two standard deviations. However, as I understood the Court's request, Special Master Baird was asking for the

Government's authoritative source in defining true microcephaly as two standard deviations from the mean. In fact, the Government produced a treatise defining two standard deviations, and in so doing, relies on the Nelson textbook.

One only has to consult p. 1303 of Nelson's textbook wherein there is a point blank definition of microcephaly: "Head size is *more than three standard deviations* below the normal mean." Margaret's head circumference, up to age of six months, was not three standard deviations from the mean, let alone greater than three standard deviations. As I testified, one must conclude that she was a small child with a small head, not microcephalic, and her short stature, by itself could never have portended the dire outcome which she suffered.

The se[c]ond core question which I have raised above becomes academic since both the Government and the Petitioner accept the authoritative nature of the Nelson textbook. For the sake of argument, the Court should understand, that clinical research in child neurology has very much changed the way we look at children with small heads. During my training we were taught that over 90% of these children would be retarded because of poor brain growth. Since then there have been several studies that implore us to re-evaluate that conclusion.

One such article appeared in *Pediatrics,* Vol. 59, No. 2, February, 1977, pp. 262-265: Sells, C.J., "Microcephaly in a Normal School Population." In that study, of 1006 students between the age of 5 and 18 years, 19 (1.6%) had a head circumference which was two or more standard deviations below the mean. When these 19 children were compared with normocephalic controls, as far as I.Q., no significant differences were found. None of these children were mentally retarded. This prompted Sells to conclude that "a small brain, as reflected by a head circumference of between -2 and -3 SD does not in itself



produce mental retardation" (Ibid. p. 264). It is this type of research which correctly led Nelson to his definition of microcephaly.

Finally, it is clear that Margaret suffers from a residual seizure disorder, her seizures beginning within 24 hours of the third DPT injection. This telling proximity is highlighted by the testimony of Dr. Kitts, and the medical record, which note normal development up to 4 months of age, and the subsequent deteriorating course.

I hope this additional information is helpful to the Court.

Sincerely,

/s/ Gerald E. Slater
GERALD E. SLATER M.D.
Pediatric Neurology

[Attachments Lodged with the Court]

IN THE UNITED STATES CLAIMS COURT

No. 90-692V

MARGARET WHITECOTTON, BY HER NEXT FRIENDS, KAY WHITECOTTON AND MICHAEL WHITECOTTON, PETITIONERS

*v.*

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEFENDANT

**TESTIMONY OF KAY WHITECOTTON FROM JUNE 4, 1991 HEARING**

* * * *

WHITECOTTON—DIRECT

[11] Q What doctor did you see at that time, ma'am?
A I saw two dotcors, Sam Benjamin and Jack Foltz.
Q And what is their designation, family physician or OB-Gyn?
A They are OB-Gyn.
Q Did you begin a normal prenatal course with them?
A I sure did.
Q Approximately how many times did you see them over that period of time?
A I saw them at least 15 times.
Q During the time that you saw Dr. Foltz and Dr. Benjamin what was your health?
A I was in excellent health.
Q Prior to your becoming pregnant how was your health?
A Excellent. I did not smoke. If I drank it was a glass of wine just occasionally.



Q How about during the pregnancy, ma'am? Any smoking or drinking?
A No smoking. No drinking at all. I took vitamins. I did everything I was supposed to do. I ate well, exercised.
Q During the time that you saw Dr. Foltz was he reporting normal progress in the pregnancy?
A Yes, he was.
[12] Q Would you characterize your prenatal period as being uneventful and normal as far as you were concerned?
A It was pleasant.
Q When was Maggie born, ma'am?
A Maggie was born April 22, 1975, at 3:28 in the afternoon.
Q Can you describe your labor?
A I went in somewhere around 7:00 in the morning and about eight hours of labor or less.
Q Would you characterize your labor as normal labor?
A Normal labor.
Q Did you have a fetal heart monitor on during labor?
A Yes, I did the entire time until I went into delivery.
Q Were you able to notice while you had the fetal heart monitor on whether or not there was a good heartbeat and no stress on the child?
A They explained it to me because I had lots of questions. I am a person that questions everything that happens to me healthwise.
Q What did you note?
A They said that it was perfectly normal and if there was any change in it I would immediately know. There was no change in it. She was doing well.
[13] Q What about the heartbeat of the child during that time?
A That was the heartbeat of the child. That is what I was watching.

Q At the time of birth were there any problems with the birth?

A Maggie was fine. She came out crying. I immediately got to see her.

Q I know the record reflects this, but I did note Apgar scores at that time?

A Yes, her Apgars were eight and nine.

Q And what perception did you have when the doctors took a look at Maggie at birth?

A My OB-Gyn said I had a beautiful, healthy, normal baby girl. Shortly after that our family practitioner came in, and he concluded the same.

Q Were you released from the hospital then a few days later?

A I was released in three days, along with my daughter.

Q After the child was born and while you were still at the hospital did the child go into any distress, put into ICU, under any type of need for special equipment or any special needs while she was in the hospital?

A None whatsoever. She visited me according to [14] their usual schedule, and I fed her.

Q Upon release from the hospital did you see a doctor or family physician, someone to care for the child after your release?

A Yes, I saw our family practitioner in three weeks and then at regular schedule.

Q Who was that ma'am?

A That was Wesley Shannon.

Q As indicated in the record, you apparently saw Dr. Shannon at intervals of three weeks, six weeks, two months and three months. Is that correct?

A That's correct.

Q During the time that you saw the doctor did he report anything unusual about the child, or were things going well up through the vaccine of August 18, 1975?

A He assured me that she was doing great.



Q During that time, ma'am, and I am talking now about the time frame between birth and August 18, 1975, if I may, can you describe the child and what you observed about the child as the child was growing up?

A Maggie was a fun baby. She was very enjoyable. I held her often. I spoiled her. She was very healthy, very normal. I was never concerned about her.

Q How about her milestones during that period of time? Did you note her milestones during that time?

[15] A She developed very rapidly. She met all the milestones that my baby book said she should be doing. In fact, some of them were early.

Q Was she able to smile at you, roll over?

A Oh, she smiled, she rolled over, she played with her feet, she put her hands together, she giggled out loud, she sat up with support on her back, she ate well.

Q Mrs. Whitecotton, did you bring this morning photographs that were taken of the child during that time period we are talking about?

A Yes, I did.

Q I will show what has been marked for purposes of identification as Petitioners' Exhibits O-1 through O-6 and ask if you could identify each of those. As you indicate the photograph, indicate the exhibit number O-1, O-2 or whatever and indicate who that is a picture and the approximate time that picture was taken.

A This is O-1. It was taken April 25, three days after Maggie was born, the day we arrived home from the hospital.

The next one is—I need a longer arm here—O-8.

Q It should be O-2. They are in order.

A Shall I get my glasses?

Q If you have them here go ahead.

[16] A This is the same day. I mean—I am sorry—April 26.

Q Of 1975?

A 1975.

Q Where did you get these pictures?

A I got these pictures from her baby album.

Q Go ahead to your next picture.

A This is O-3 dated April 26. These were taken by her grandmother. The next one is early August, pre-DPT, and it is O-4. She is having a little cry there.

Q How do you know that that was taken at that time?

A It was posted in my baby book.

Q Go ahead, ma'am.

A The next one is O-5, early August, 1975, and she is on the sofa sitting propped up. The next is O-6, early August, 1975, the same thing.

Q Do those photographs fairly and accurately depict your daughter, Maggie, during that period of time you have referenced?

A I'm sorry?

Q Do these photographs fairly and accurately depict Maggie during that period of time we have referenced?

A Most certainly.

MR. CAPPER: I guess they are already moved into evidence.

* * * *

[18] Q On August 18, 1975, if I could call that to your attention, do you remember and recall Maggie and recall her condition prior to the vaccination that day?

A She was well when I took her to the doctor. It was her normal check-up.

Q Did Dr. Shannon administer the DPT shot at that time on August 18?

A Yes, he had administered all of them himself.

Q Approximately what time of day was that, if you recall?

A It was shortly after noon.

Q After she received the shot did you proceed home that day, or what did you do?

A I do not recollect that, but I would assume that I did go home.



Q Did anything unusual occur after the shot that day?

A Not until around 6:00 that evening when we were out for our walk. She appeared to be a little fussy, so we walked outside. I felt her move first, and she was going—this is the best way to describe it.

Q For the record, Mrs. Whitecotton, you are describing flinching or jerking of the upper extremities and blinking of the eyes. Is that correct?

A Right.

[19] Q How many times did that type of movement occur, ma'am?

A It occurred three or four times before I realized that something was drastically wrong. Then I went to the ER at Crawfordsville.

Q When you say occurred two or three times, was that at different intervals?

A Twenty to 30 minutes apart.

Q Twenty to 30 minutes apart?

A Yes.

Q This jerking of the upper arms and blinking of the eyes as you have described occurred how many times then on August 18, 1975?

A Three or four.

Q Did the child have a fever at that time, as far as you know?

A No. I had taken her temperature myself, and it was just around 100. At the ER they also took it rectally, and it was around 100.

Q Did the child sleep through the night?

A She did sleep through the night. She slept well, and I checked her frequently to make sure that she was doing well.

* * * *

[25] A May I revert back to one situation at Riley?

Q I do not know what you are referring to.

A When we were in the ward and it was a concern of mine when she projectile vomited for the first time across the room. I didn't realize what it was. She had never done that before.

Q And that was at Riley Hospital?
A That was at Riley.
THE COURT: How is Riley spelled?
THE WITNESS: R-I-L-E-Y.
BY MR. CAPPER:
Q The records that are part of the exhibits here, Mrs. Whitecotton, show at the top Marion County General Hospital on one side and Indiana University Hospitals on the other. Is Riley Hospital part of the Indiana University hospital system?
A That's correct. That's correct.
Q So when we refer to Riley Hospital we are talking about those record that may show Marion County General Hospital/Indiana University Hospitals, correct?
A That's right.
Q Did you note then as time went along after August 18, 1975, any change in Maggie with regard to her health and with regard to her development?
[26] A Healthwise the one thing that stands out in my mind most of all is the fact that projectile vomiting became a very frequent event in our home.
Q How about her development?
A Developmentally the milestone that she had so easily reached prior to the DPT shot became scattered, and sometimes she just, you know—in fact, at one point in time before the shot she was raising her little feet up in front of her hands. She no longer did that.
Q Any other specifics like that or things that she was not marking or making in terms of milestones or observations you made, if any?
A Well, I don't know how to explain it, but slouchy. She was so erect before. She just became slouchy, for a better term.
Q I will now show you what has been marked as Petitioner's Exhibits O-7, O-8 and O-9 and ask if you can identify those for the record, please.
A Yes. O-7 is Maggie at one year.



Q And this is subsequent to August 18, 1975?
A Right. O-8 is Februray, 1976, and O-9 is Christmas of 1975.
Q And again, you got those photographs from her baby book or baby album?
A Right.

* * * *

[29] BY MR. CAPPER:

Q As time has gone along here since August 18, 1975, can you describe Maggie's condition, her health and her progress up through the present time?
A I am sorry, John.
Q Can you describe Maggie's health and Maggie's progress since August 18, 1975, to the present generally?
A Well, generally she is moderately to severely retarded. Her progress is very slow.
Q Is she able to communicate, Mrs. Whitecotton?
A To her family.
Q You say to your family. I do not know what that means?
A She is non-verbal.
Q Non-verbal? Okay. Is it required that she have someone with her in attendant care at all times?
A Yes.
Q Does the videotape that we submitted as an exhibit fairly and accurately depict how Maggie is today in terms of her ability to move about and ambulate, among other things?
A Yes. She is not able to even be helpful and ambulatory.
Q Did you begin noticing anything about the child with regards to her hands or legs or anything after the August 18, 1975, vaccination?
[30] A I noticed that she no longer pulled her little legs up to play with them like she did before. She was frail. She didn't eat as well. She was able to mechanically eat the food. I mean, that wasn't the problem. Her

problem was the fact that she would get a lot of mucus and then projectile vomit.

We had a very difficult time finding people to take care of her because she would stress them out so much because she would cry constantly with them. She was very fretful—I guess that is the best word—from that moment.

Q There has been some indication, I believe it is F-6 or something in the exhibits, that you made mention at some point in time to the doctor, and I do not think the doctor observed this, but you made mention to the doctor at some point that you may have noticed on one occasion or another leg jerking or something in the past. What did you observe, and when did you observe that effect?

A She was napping when I noted it. There would just be a little jerk of her leg. It wouldn't wake her up. I did not think anything about it at all other than a normal childhood behavior.

* * * *

[35] Q And at that time did they measure Maggie's length and height and head circumference?

A As they did my son; as they do every child.

Q And they never said anything to you about her head being unusually small?

A No.

Q Did you ever observe Maggie having swallowing difficulties before she was four months old?

A No.

Q Are you aware that there is a medical record that says in the patient's history that she had swallowing difficulties since birth?

A I believe that is Dr. Hwang, is it not?

MS. HIDALGO: Yes.

Let me direct the attention of the Court. That is Exhibit H-12, Page 3.



## WHITECOTTON—CROSS

BY MS. HIDALGO:

Q Did you ever have discussions with Dr. Hwang?

A Dr. Hwang was her pediatrician, yes.

* * * *

[41] Q So you noticed projectile vomiting the first day that she was hospitalized or the second day?

A Well, I don't know that either. I can't recollect that.

Q Did you see her projectile vomiting only once?

A I was holding her. That was the only time I saw her do it at Riley. I asked the nurse. I remember what I said. I remember making a face. I remember seeing it on the floor. I said what is this crap? That is the words I used. It was like an oil slick. You could just push it around the room. It was just awful stuff mixed with formula. I had never seen it before.

Q When you say it was like oil, was it like mucus?

A It was mucus and milk. It was horrible stuff.

Q You said you spoke with a nurse. Did you talk to a doctor about this also?

A I told the nurse, I said please tell the doctor about this. I had not seen her medical records until this year, and I see nothing in the records that tells me that the nurse told the doctor.

* * * *

**TESTIMONY OF ELLEN KITTS, M.D.**
**FROM JUNE 4, 1991 HEARING**

KITTS—DIRECT

* * * *

[60] Q Dr. Kitts, I am going to show you some photographs that have been previously introduced through Maggie's mother. I will show you these in sequence.

I show you what has been marked for purposes of identification as Petitioners' Exhibit O-1 through O-6. I would like for you to just look at those. I will tell you for the record that those have been identified as Maggie Whitecotton pre third DPT vaccination from early childhood to late July or early August of 1975. Could you please review those photographs?

A In my practice I frequently am asked when does something happen, when did a child develop cerebral palsy or when did they have their stroke. In my practice I routinely [61] ask patients to bring photographs to me because sometimes I can get information from that.

The first one that I have marked O-1 is dated April 25, 1975. This is a newborn infant. The hands are held close to the face so that her elbows are flexed, but the fingers are open. The hands are relaxed.

Q What does that tell you, doctor?

A This is normal posture for a newborn infant.

Q Would that indicate cerebral palsy or brain damage at that stage?

A No, I see no sign of any brain dysfunction in this picture.

Q What about the next one, O-2?

A The next one is O-2. Again it is a newborn infant being held. Again this looks like a normal newborn infant. The hand is relaxed. It is open. The fingers are open. The arms are again held close to the face. This is a picture of a normal newborn.

Q The next photograph?



A This is O-3. Again this is a newborn. This time the shoulders have been flexed so that the hands are extended up above the head.

Q What does that tell you, doctor?

A Children with cerebral palsy do not have the capabilities of being this relaxed and having the hands in [62] that position. Children with cerebral palsy have a lot of difficulty getting their shoulders to move so that their hands are always down rather than being relaxed and up.

The next one is O-4. In O-4 Maggie is obviously crying and very unhappy. In this position again her overall body is overall relaxed. Children with cerebral palsy, the more emotionally upset they become the stiffer they become, the more their arms straighten, the more their hands fist, the more their thumbs tend to go into the palm. Again, even though she is obviously really upset her hands are open and relaxed. Her thumbs are widely out of the palms. The muscles of facial expression are working well. This again is a normal picture.

Q Do you have O-5 there?

A Yes. In O-5 she is prop sitting supported by a pillow. Again, this is a very normal for this aged child. The legs are relaxed. They are bent a little bit. The feet are in a normal position. They are not pointing toe down. The arms are relaxed. The hands are open. The fingers are relaxed. Again, this is a very normal picture.

The last one I have is O-6. In this one she is being held supported, but she has excellent head control. She has her hands together in midline. She is playing with her fingers. Her hands are open. Again, this is a nice developmental picture, and everything looks normal. That is [63] four months of age.

Q Doctor, what would you expect if you had a child in those pictures? If you were to look at those pictures now and had a child that the doctor claimed she had cerebral palsy what would you expect to see in those pictures?

A I would expect to see either too much stiffness or too much looseness. For the children that are too loose and are floppy they don't have head control. They don't have the ability to hold their arms against gravity, so they can't really flex them, which she has done nicely. You may see side to side differences or changes in the face. Again, none of those changes are present.

In a child that has too much stiffness the hands are always fisted, and instead of just being a normal fist usually the thumb is inside the fist, which is called cortical thumb, and again is a sign of brain damage. The more angry they become the stiffer they become and the more the fist tightens. Often times the more the elbows straighten they are not able to get their hands or arms up above their head.

Children with too much stiffness tend to have their legs go straight out. They are not able to bend their knees. Their toes are pointing straight ahead. They are not able to relax their ankles and bring their feet up. In these pictures I don't see any signs of any of those [64] problems.

Q Do you see any signs of brain damage?

A No.

Q Doctor, I want you to look at some photographs that have also been identified by the mother. They are marked for identification purposes as Exhibits O-7, O-8 and O-9.

I will tell you again that those are photographs that have been identified by the mother as Maggie Whitecotton, the Petitioner in this case. I believe the dates are indicated on the back, but those were taken after the third DPT shot of August 18, 1975.

Will you take a look at those and identify the photograph as you go through those, please?

THE COURT: Start with O-9 if you will because I think that is the oldest. I think they are in reverse order.

MR. CAPPER: Okay.



THE COURT: O-9 was Christmas of 1975.

MR. CAPPER: That is right.

THE WITNESS: In O-9 Maggie is being held by her mother, and at this time mother is giving her more support than she was in previous pictures.

* * * *

[68] Q And the delivery was uneventful?

A That's correct.

Q She had Apgar scores of eight and nine, correct?

A That's correct.

Q What about Apgar scores of eight and nine? As you look at those initial pictures, O-1 through O-6, does that correlate?

A Apgar scores describe the amount of difficulty the child is having with the delivery. If it is a real difficult delivery on the child and the child is being really stressed then the Apgar scores will be low.

Apgar scores above seven are considered normal and are not associated with any sort of neurologic impairment or neurologic damage. Apgar scores below seven, the children are at high risk to have had neurologic damage because of the stress of the delivery. These Apgar scores are completely normal.

Q So it would be your opinion, based upon a reasonable degree of medical certainty, that there was no neurological damage at birth based upon Apgar scores and the other medical information you have?

A That's correct.

* * * *

[74] Q Having reviewed the medical records information, having looked at the pictures pre third DPT shot, having heard the testimony of Maggie's mother with regard to the child's condition and her milestones and based upon your experience and training do you have an opinion as to whether or not Maggie had suffered from cerebral palsy or brain damage prior to August 18, 1975, based upon a reasonable degree of medical certainty?

A In the history that I have, in the records that I have and in looking at these photographs, which is my only connection with Maggie at this early an age, I see no sign of any brain damage or no sign of any cerebral palsy from early August of 1975 and prior to that.

From birth through early August of 1975 the medical records that I have and the pictures that I have are all of a normal infant without any signs of cerebral palsy, without any signs of brain damage.

THE COURT: Let me just interrupt here for a second. I am not sure her answer was responsive to your question, and I want to make sure for the record that I understand what it is she is saying.

He asked you if you had an opinion to a reasonable [75] degree of medical certainty as to whether or not there was brain damage, I believe, prior to August 18, 1975. Do you have such an opinion?

THE WITNESS: I do have.

THE COURT: And what is you opinion?

THE WITNESS: There is no brain damage prior to August of 1975.

THE COURT: Thank you.

BY MR. CAPPER:

Q Doctor, you have had a chance to review the medical records as they confirm and relate seizures that were observed by the mother the day of the vaccination, which would have been August 18, 1975, have you not?

A Yes.

Q And also you have had a chance and an occasion to review the records and report of Dr. Baird confirming additional seizures the following day of August 19, 1975, have you not?

A Yes.

Q The following day meaning the day after the vaccination? Is that correct?

A Correct.

* * * *



**TESTIMONY OF GERALD E. SLATER, M.D.**
**FROM JUNE 4, 1991 HEARING**

SLATER—DIRECT

* * * *

[157] Q What conclusions can you draw from those photographs?

A I don't draw the conclusions that Dr. Kitts does. To me they are not all that helpful. What I do see is a persistence of cortical thumbs subsequent to four months, which I don't see prior to three to four months.

Cortical thumbs are a fisting with the thumbs in palm. It is an abnormal motor tract sign. That is all it speaks to. It is called cortical thumbs. At birth if it is intermittent it is normal. If it is persistent it is always abnormal. At birth you overlook a child who shows cortical thumbs intermittently. You never overlook it if it is persistent.

That is all I see from this. I don't know about obliquitonic neck reflex from a single picture.

Q You will leave that to Dr. Kitts?

A I am not going to testify to that.

Q Doctor, you have also reviewed the records of Riley Hospital upon Maggie being admitted to Riley Hospital in August of 1975—

A I have.

* * * *

SLATER—CROSS

[179] BY MS. HIDALGO:

Q So if the child suffers a trauma which will result in microcephaly, when does one document the microcephaly after the trauma?

A Good question. It is hard to say. Depending on the severity of the trauma, I would think it would be from several weeks to several months. If it is a minor trauma it may take several months. A severe trauma it is going to take a week or two.

Q So if the medical records demonstrate that the child deviated on the 20th of August does that not tell you that the trauma occurred sometime a week or more before that?

A Something was clearly happening to the child [180] before. Whether it was clear-cut secondary microcephaly depends on whether we are going to go with two or three standard deviations.

You are right. Something is clearly happening between three months and four months.

Q So something clearly happened before the DPT was administered?

A Something is happening if you believe two standard deviations. If you go with Nelson's three standard deviations, then nothing happened until six to eight months.

Q Regardless of whose deviation we are taking there is a change? She is no longer on the second percentile?

A That's true. She is slightly below the second percentile at four months.

Q You said in your letter to Mr. Capper dated March 24, which is Exhibit L, at the bottom you say—

A At the bottom of what page?

Q I am sorry, the first page. You say, "She then suffered impaired brain growth, and her head circumference fell off its normal curve. This is termed secondary microcephaly, and it implies a postpartum injury to the brain at or around three months of age."

A Right.



**TESTIMONY OF OWEN B. EVANS, M.D.**
**FROM JUNE 4, 1991 HEARING**

EVANS—DIRECT

* * * *

[206] Q What conclusions have you drawn from your review of the Petition, affidavits, medical records and the additional materials?

A It is my opinion that Margaret Whitecotton had a congenital organic brain syndrome that was characterized by microcephaly, mental retardation and cerebral palsy with epilepsy and that this was the result of prenatal factors.

MR. CAPPER: I am sorry. I did not hear that, doctor, the last part.

THE WITNESS: It is a result of prenatal factors.

MR. CAPPER: Okay.

BY MS. HIDALGO:

Q You indicate in your letter to me that you consider Margaret microcephalic. Is that correct?

A That's correct.

Q When, in your opinion, did she become microcephalic?

A She was at the second percentile at birth, which is at two standard deviations below the mean. That definition is microcephaly.

Q So your definition is at the two percentile or below?

[207] A At two standard deviations or below. Two standard deviations is approximately 97.5 or 97.6 percentile, or if you go to the other end it is going to be approximately from the 2.3 to the 2.5 percentile. She was at the second percentile, which would be at or below the two standard deviations.

Q Is it your opinion that Margaret was microcephalic before receiving the DPT shot on August 18, 1975?

A Yes.

Q What is the etiological origin of Margaret's serious neurological deficiency?

A This would come in the category of primary microcephaly. There are many factors which can cause that. Some are familial, some are diagnosed intrauterine insults, and then there is a large proportion which are just unknown.

Q What do you mean by chronic organic brain syndrome?

A This is a non-progressive developmental disorder of the brain. It is characterized by impairments of cognition, motor activities, learning and often associated with epilepsy or similar types of phenomenon.

Q Did you say it was non-progressive or progressive?

A Non-progressive.

Q What do you mean by that?

A In that [t]he deficits are fixed. That is, the [208] child's intellectual impairments and motor impairments and other things do not deteriorate with time. The child is born with a fixed deficit.

Q What evidence in the medical records supports this medical opinion of yours?

A The major evidence is the small head. I think almost all authorities would agree that a child that is microcephalic is inherently at risk of having severe developmental disorders such as cerebral palsy and mental retardation.

The other points in the record are the history of lifelong feeding difficulties, the history of seizures and the subsequent diagnosis of cerebral palsy and mental retardation.

Q Can you identify where in the medical record there is a reference to feeding difficulties?

A Yes, if you will give me a moment here. This would be under I think it is Exhibit H-11. No, I am sorry, H-12, Montgomery County Culver Union Hospital of 8-29-79. It is located on my Page 3, which I assume is the discharge summary. It says past medical history—past history, medical.



MR. CAPPER: What page is he on?

THE COURT: Page 3.

MS. HIDALGO: Three.

[209] MR. CAPPER: Just for clarification, is that Dr. Hwang's history?

THE WITNESS: It is Dr. D.S. Hwang, H-W-A-N-G.

MR. CAPPER: That is Hwang in Crawfordsville.

THE COURT: Go ahead.

BY MS. HIDALGO:

Q Why is that significant, Dr. Evans?

A Because children with cerebral palsy and mental retardation often present with feeding difficulties because of the poor coordination of all their musculature, including that of sucking and swallowing.

Q Is there a relation between microcephaly and mental retardation?

A Yes, there is a very close relationship. It varies on the author that you read, but for example, Menke in his textbook says virtually 100 percent of children with microcephaly have mental retardation. That is probably a little bit too extreme. Most of them would say upwards of 90 percent or perhaps 95 percent will have microcephaly.

Looking at it the other way around, if you look at the microcephalics and try to find out how many of those will eventually have normal intelligence it is only 7.5 percent of those. Most of those are the familial types; that is, the parents had microcephaly as well, and the child inherited that as an autosomal dominant trait.

[210] Q Is there a relation between microcephaly and cerebral palsy?

A Very much so. The children who are microcephalic have evidence of brain destruction or brain undergrowth. As a result of that they have impaired motor functions so that cerebral palsy is found in a large percentage of children with microcephaly.

Q A child who is born with microcephaly, is it common for them not to exhibit any sort of cerebral palsy or neurological disorder in the first few months?

A That is often the case. A child's abilities are not noted to be lacking until they are what is called developmentally recruited. For example, you are not going to know if a child is going to walk or not until after anywhere from 12 to 18 months of age because you don't expect a child at two months or three months to have normally the ability to walk.

There is one study that said about 36 percent of children thought to be neurologically normal at four months of age turned out to be neurologically abnormal. That doesn't mean we are not good examiners. It just means that many of the signs and symptoms that appear later in development—excuse me; many of the abilities that appear later in development—are just not detectible early on.

* * * *

[213] Q What is that opinion?

A My opinion is that she did have seizures to answer your first question, and the second question, my opinion is that these seizures were related to her chronic organic brain syndrome or chronic encephalopathy and not related to her DST immunization.

Q Do you hold that opinion to a reasonable degree of medical certainty?

A Yes.

Q What evidence is there in the record to support your opinion?

A My primary evidence is the clinical picture of her multitude of developmental disabilities, which include the cerebral palsy, the mental retardation, the microcephaly. In that group of patients epilepsy is an extremely common event. Up to 33 percent of them will have seizures along with their other developmental disorders.

I do not see any evidence that the child suffered an encephalitic or encephalopathy at the time of her immunization to think that she had an acute neurologic deficit with it in which the seizures would be a symptom



of that, so it is my opinion that these seizures were independent of the DPT immunization.

* * * *

[219] BY MS. HIDALGO:

Q Dr. Evans, of these three charts do they all reflect the child being at the two percentile in the first two months then below the second percentile after the third month and getting lower and lower from the second percentile thereafter?

A That is correct.

Q Is that consistent with a child with primary microcephaly?

A That is correct.

Q Is that consistent with a child who has chronic organic brain syndrome?

A It is one of the signs of chronic organic brain syndrome. Not necessarily will every child with chronic organic brain syndrome have microcephaly. A small percentage of them won't. Some children with chronic organic brain syndromes will have a normal head size.

Most children, the vast majority of children, with microcephaly will have mental retardation and these other problems.

Q With respect to the seizures that Margaret sustained on August 18, 1975, what, if anything, do they indicate?

A In my opinion it indicates another symptoms of her chronic encephalopathy. In other words, they are a symptom [220] as is cerebral palsy, as is mental retardation.

Q In your opinion did the seizures percipitate the microcephaly?

A No.

Q Have you drawn any conclusions about the temporal relationship between the administration of the vaccine and the child's seizures?

A It is my opinion that those were coincidental and not causally related.

Q Is there any evidence in the record showing that the episode of seizures on August 18 and 19, 1975, caused the problems identified in Margaret's first year of life, namely mental retardation and cerebral palsy?

A No, there is none at all.

Q Is it your opinion that the seizures of August, 1975, had little, if any, effect on Margaret's neurological deficiencies?

A No, it is my opinion it does not. The seizures that were described in the record were brief. They involved usually an extremity, or they involved staring and unresponsiveness. To my knowledge and in my experience, that does not cause brain damage.

The only way that one can ascribe brain damage from seizures is one, if it is very prolonged with generalized tonoclonic activity or a grand mal seizure that [221] impairs respirations to the point that the brain does not get sufficient oxygen. That certainly is not described in the record.

Another theoretic possibility is repeated seizures over many days, months or years that might impair the metabolic activities of the brain and cause some brain function deterioration.

In large studies, for example, the perinatal study with the NIH in which they looked at children who had grand mal seizures and repeatedly so with fevers, they did not have any differences in their ultimate IQ or other neurologic deficits. Even in the worst case seizure scenario, brief occasional seizures do not appear to have any adverse affect on the brain.

Q In your opinion, were those seizures consistent with the pre-existing microcephaly?

A Yes, they are.

Q Excuse me?

A Yes.

THE COURT: Did you say you guess, doctor?

THE WITNESS: No, I said yes.



THE COURT: Excuse me.

BY MS. HIDALGO:

Q Do you hold that opinion with a reasonable degree of medical certainty?

[222] A Yes.

Q What other neurological disorders are typically associated with microcephaly?

A The major ones are those of cognition, which usually relates to mental retardation or learning disabilities, and the other one is motor impairment, which usually is characterized by in the subtlest form clumsiness or incoordination and in the most serious forms as cerebral palsy. Many children also have behavioral disorders associated with it as well.

Q Assuming that the seizures resulted from the August 18, 1975, DPT vaccination, is there any evidence to indicate that those seizures aggravated Margaret's pre-existing microcephaly?

A No, there is no evidence. I will go back to my previous answer that the seizures as described, in my experience and reading, would not in any way cause significant brain injury or anything else. Further, there was no history by description coincidentally with those seizures that the child was suffering from an encephalitis or acute encephalopathy.

There was one mention in the record that the child had been seen the day before in Crawfordsville or whatever, and the examination was stated to be normal. I believe in the examination when she was hospitalized for the seizures [223] there was no indication that the child had encephalitis or altered consciousness so that the seizures were not of a type that would cause brain injury, and they were not a symptom of an acute encephalitis or encephalopathy that would cause brain injury.

Q Have you seen or treated other patients with chronic organic brain syndrome?

A Yes, I have.

Q Have those children been microcephalic?

A Many of them have, yes.

Q Have they exhibited signs and symptoms consistent with Margaret's?

A Yes, and in every way.

Q About how many children would you say you have seen with chronic organic brain syndrome?

A If one includes all children with cerebral palsy and mental retardation together it would probably number in the hundreds, if not more, at our general pediatric neurological clinic, in which we receive the majority of referrals throughout the entire State of Mississippi, and also at the crippled children's clinic, which receives a good portion of referrals, and at our children's rehabilitation center, in which many children with cerebral palsy and similar problems are admitted.

* * * *

[226] BY MS. HIDALGO:

Q Are children with microcephaly more likely to have seizures resulting from a febrile illness rather than an afebrile illness?

A Yes.

Q What I am actually getting at is do fevers often induce seizures in microcephalic children? Is that common?

A Fever induces or are more likely to induce seizures in any child who has epilepsy or is seizure prone. I wouldn't necessarily say it is more likely in a microcephalic child than another child who has epilepsy or is seizure prone.

Q On what do you base your opinion that the seizures of August 19, 1975, did not aggravate Margaret's preexisting chronic organic brain abnormality?

A Again, for two reasons. One, the seizures as described in the medical record are not those that are associated with brain injury. Secondly, there was no other signs of an acute encephalitis in which the seizures would simply have been a symptom of a more serious brain injury.



I see nothing in the record that would indicate that the seizures in and of themselves caused any brain damage.

Q Is there any evidence that the seizures accelerated her cerebral palsy?

[227] A No, there is no evidence for that.

Q How would you compare Margaret's course with the normal course of a microcephalic child who had not had any DPT complications?

A I would say all things considered they would be very typical for any other child that had cerebral palsy, microcephaly, mental retardation and epilepsy. They would be identical.

Q Do you have any opinion as to why a chronic brain abnormality was not raised as a possible etiology during Margaret's hospitalization?

A In my opinion it was raised because they identified the child as being microcephalic. That was clearly stated, and I think for good reason. The child was clearly microcephalic by anybody's definition at the fourth month. That certainly couldn't have been induced by the DPT that was given that very day.

The second reason is that I think the child came in hand with the diagnosis of DPT related seizures. I think that that was a general assumption at the time.

Finally, I don't think that the child—as I mentioned earlier, the neurological examination—with her degree of cerebral palsy and mental retardation would necessarily been detectible at four months.

Q In your practice have you encountered a child with [228] cerebral palsy secondary to a chronic brain abnormality which has been as serious as Margaret's?

A Much more serious in many cases.

Q About how many cases?

A With the typical picture of microcephaly, cerebral palsy, mental retardation and epilepsy, with all those things combined there have been at the minimum dozens of patients very similar or more severe.

Q Have you had an opportunity to review the medical opinions of Dr. Slater and Dr. Kitts?

A Yes, I have.

Q Do you have any comments?

A Yes, if you can give me a moment to pull those up. I think this is Dr. Slater's, and I think it has been marked Exhibit L and N. I think L is his statement. I think N is his CV. Do you all have that?

On the third paragraph of the first page of Dr. Slater's comments it says, "Her head circumference grew exactly at the second percentile through the first three months of life. At four months of age her head circumference was for the first time off the growth chart and clearly below the second percentile."

* * * *

EVANS—CROSS

* * * *

[237] Q Do you believe there is a causal relationship between the pertussis vaccine and a person having an adverse reaction?

A Yes, I think there are adverse reactions to a pertussis vaccine.

Q Is that even though you indicate in your report that there are no control studies that have shown as association between immunizations and progressive or chronic neurologic disease?

A I am sorry. What is the question there, Mr. Capper?

Q The last page of your letter, the third paragraph from the bottom, your last sentence says, "Furthermore, there are no control studies that have shown an association between immunizations and progressive or chronic neurological disease." Do you still believe that?



A Yes.

Q So it is your opinion then that really there are no studies that shown the association between these DPT shots and chronic neurological disease?

A Well, there are studies that have shown it, and there are studies that have not it. There are studies that [238] reviewed studies that have not shown it.

Q I am asking you, though. Your statement is—

A It is my opinion that there are no control studies that well document association between immunization and progressive or chronic neurologic disease.

Q And is that your feeling also? I mean, you are saying the studies. Is that your feeling also?

A That is my opinion in reviewing the studies, yes.

Q Do you find that to be, applying in the face of our purpose here today, to believe there are no control studies associated between immunizations and chronological neurological disease and the fact that Congress has passed this Act believing that there is that relationship?

A I am not here to debate what Congress says. I mean—

Q But on that basis, if they are assuming that fact, that connection, do you find that to put some suspect in your opinions—

MS. HIDALGO: Objection.

THE COURT: Allow him to finish the question.

* * * *

[240] Q And if you believe there are no studies that show any connection and we are here in a program that says there is a connection, does that not taint your testimony then before this Court—

A Counsel, I don't think it taints my testimony at all.

Q Just a second. Just a second. —as to whether or not there is a causal connection?

A I am not sure that Congress established a cause. Congress established a program in which—

Q That was not my question.

THE COURT: Allow the witness to answer the question.

THE WITNESS: I don't think the vaccine law states that there is a causal effect. It just sets up a compensation mechanism for children who have had various and sundry events occur in relationship with DPT. I don't think that it states that it does cause it.

My opinion is my opinion, and that is I do not think it causes it, and I don't think it applies in the face of anything. That is my opinion.

BY MR. CAPPER:

Q But is it not a fact that when you have a predisposed opinion that when you look at facts—medical [241] records—then you can look more favorably to those in making your opinion having that predisposition?

A Well, that assumes my predisposition was made prior to reviewing the records. My feelings are cumulative over reviewing many documents that have come out.

For example, our own Child Neurology Society had a group of concerned people and experts, and their opinion was published just this April. Another opinion came out in the medical literature in the Journal of Pediatrics came out in March. Those go into my thinking about this. I believe I was assigned this case sometime late last fall.

Q But you still believe there is no connection, do you not, doctor?

A Yes. After reviewing all the material available and the literature it is my opinion at this point.

Q No, I am talking about your opinions themselves of the causal connection.

A Yes, and my opinion is subject to change if another articles comes out that shows more scientific validity than—



Q But I am saying right now.

A Right now that is true.

THE COURT: He has stated clearly what his opinion his, [*sic*] counsel.

MR. CAPPER: Okay.

[242] BY MR. CAPPER:

Q Doctor, are you familiar with the national vaccine program and the fact that Congress, through the Secretary, has established this program among other things to achieve optimal prevention against adverse reaction to vaccines? Are you familiar with that?

A I am not familiar with the details of legislation.

Q At 42 USC 300A-1?

A I am sorry. I am just not familiar with—I have not read the actual legislation. I think I have read the guidelines that come along with this, but I have not read the entire Act.

Q The reason I ask that, doctor, is because a lot of your testimony deals with this microcephaly question and the fact that it is your belief that microcephaly existed from the time of birth, correct?

A That's correct.

Q Having this predisposition as you review the record and as you review the plotting on the growth charts, is it not a fact that the plotting on the growth chart is very, very close and very, very minute as you do that plotting when you look at the head charts in the record at age seven?

A Yes, it is close.

* * * *

[247] Q Looking at H-7, the fourth page, do you have that in front of you?

A H-7? Would you describe what that one is?

Q That is a head growth chart, the big one.

A The big one that says Head Circumference—Girls at the top?

Q Yes.
A Yes.
Q Shortly after birth the child is still on the chart, correct?
A According to this two standard deviations.
Q It is not greater than, though, is it?
A What?
Q It is not greater than two standard deviations, is it?
A No, it is on the second percentile.
Q So according to Menke's definition of microcephaly then that would not be a microcephalic reading, would it?
A Well, according to his definition of being greater than, no, it would not.
[248] Q And according to Nelson it would be either since his definition would be three standard deviations, correct?
A By that definition, no, it would not.
Q Looking at two months of age, under Nelson and Menke we would still be in a situation where under their definition it would not be microcephalic child. Is that correct?
A By those two definitions that is true.
Q At three months, looking at the chart, under Nelson and Menke we would not be under the definition of microcephalic, would we?
A On my graph she would be.
Q No, I am not talking about your graph. I am talking about—
A I am talking about your definition. On this graph she would be.
Q I am looking at it, sir, and that is a dot right on it.
A Which month are you talking about?
Q At three months of age.
A This one does not have a dot at three months.

* * * *



[254] Q Is it my understanding that the record shows that from birth through the first four months if we exclude the fact of microcephalic for a minute that the child had normal growth and normal development?
A Well, there is that reference I alluded to earlier about having feeding difficulties from birth, and then there was another reference from—
Q Let's talk about the feeding difficulties real quickly. That is Dr. Hwang, who saw the child in 1984, is it not?
A That's correct.
Q Other than that doctor, of the doctors that saw this child directly immediately after birth and through the first year of life, did any of those doctors indicate she had feeding difficulties?
A I think there was an implication on that during that one at a later time when she was—
Q My question, doctor, is did you find that the record showed that in fact she had that by her treating physician or any other—
A No. That is the one that I recall.

* * * *

[262] Q And now you are going to say again it is your testimony and opinion that it is purely coincidental that this child had seizures—three or four the night before, one witnessed by a doctor the next day—and a temperature less than 102 degrees and that that is all purely coincidental, sir?
A Absolutely. If I might add—
Q Well, there is no question before you, sir.
THE COURT: If you want to expand on your answer you may do so, doctor.
THE WITNESS: The reason I am stating that is that we see many other children with microcephaly, cerebral palsy, seizures, mental retardation, who start having seizures that are unrelated to anything else that one can make a causal association with—the fullness of the moon or anything. I mean, children with this condition start seizuring at some point.

In early childhood when you are given an immunization every month for three months there is a high likelihood just statistically you are going to hit upon within two or three days or a week of a previous immunization.

* * * *

[279] THE COURT: Where did you come up with it?

THE WITNESS: I have always used it. I guess I learned it where I trained.

THE COURT: Is it a defined medical condition?

THE WITNESS: In the sense of legal? I think any child neurologist would know what one was talking about.

MR. CAPPER: I am going to object to the answer as being non-responsive to the question.

THE COURT: Well, do not waste time objecting. The answer is going to stand. I thought it was responsive.

Were there any signs prior to August 18, 1975, that such a condition existed in Maggie Whitecotton?

THE WITNESS: Other than the things I alluded to earlier—the microcephaly, which I think she had, and the statement that she had chronic feeding problems.

THE COURT: Did you say that the likelihood of a person developing seizures who has microcephaly is 33 percent?

THE WITNESS: Yes, sir, I believe that is the figure that is sometimes used.

* * * *

[282] THE COURT: And what is the evidence of brain undergrowth here, if there is any.

THE WITNESS: The small head. The head size reflects the brain size.

THE COURT: Would an EEG show brain undergrowth?

THE WITNESS: No, sir.

THE COURT: Would a CT scan?



THE WITNESS: The CT scan could show a small brain. That would really not add anything than your small head.

THE COURT: The same thing for an MRI?

THE WITNESS: Yes, sir. It may show more. It may show heterotopias—that is, islands of cerebral gray matter that did not migrate to the cerebral cortex. It may show malformations of the corpus callosum or other things that are commonly associated with a chronic organic brain syndrome.

THE COURT: You have talked about this to some extent. What is the etiology of primary microcephaly?

THE WITNESS: There are several charts and tables which outline a variety of things. Perhaps the most common we see is idiopathic. That is, the child is just born with a small head. We don't know why.

* * * *

[286] THE COURT: But you do not think that as a stressor on the body with a fever it would cause seizure?

THE WITNESS: No.

THE COURT: So do you think looking retrospectively at this case that that is an incorrect diagnosis?

THE WITNESS: Yes.

THE COURT: Was it an improper diagnosis to consider at the time?

THE WITNESS: I am not sure if it was improper because I think at the time there were a lot of opinions circulating that DPT was commonly associated with seizures. That was about the period of time that the first British survey came out. Certainly there was a long anecdotal history leading up to that point.

I think a lot of people, perhaps including myself, at that time assumed there was a causal relationship.

THE COURT: When you came into this case did you at that point have an opinion as to whether or not the DPT vaccine causes permanent neurological disorders?

THE WITNESS: I think if I remember correctly it [287] was my opinion at the time that it did not.

THE COURT: So your opinion has not changed during the last year or so?

THE WITNESS: No, I don't think it has changed, but in all honesty, I do try to keep an open mind when reading literature.

THE COURT: Does the fact that you have that opinion affect the opinion you reached in this case as to whether or not Maggie was microcephalic at any time during her life?

THE WITNESS: That has no bearing on that whatsoever.

THE COURT: Does it affect your opinion as to whether or not at encephalopathy occurred within three days following the vaccination on August 18, 1975?

THE WITNESS: No. There is no fact of that. I can't remember the case, but there was another pertussis case. It was not related to this. It is my opinion that I would allow a pertussis immunization if there was a sign of brain injury at the time; that is, altered consciousness and things of that nature. I would be open enough to say that that is a possibility.

* * * *



HOOSIER NEUROLOGY, P.C.

[Addresses Omitted in Printing]

September 11, 1991

John Capper
Attorney at Law
108 North Green Street
Crawfordsville, Indiana 47933

RE: MARGARET A. WHITECOTTON
DOB: 04/22/75

Dear Sir:

I am writing to you in regards to Margaret Ann Whitecotton and to her medical condition in 1975, when she suffered an adverse reaction to DPT immunization. The patient's adverse reaction to the DPT immunization is described in her hospital records when she was hospitalized at Riley Children's Hospital in August, 1975 under the care of Drs. Drew and Wissman on the neurology service.

Her hospital records include some laboratory studies that confirm the presence of demyelinating central nervous system disturbance which is characteristic of the problems associated with adverse reactions to immunization. The CSF studies performed at the time of her initial insult, August 22, 1975, show changes that are characteristic of a CNS demyelinating disease as expected from the adverse reaction to the DPT immunization.

The patient's seizure, encephalopathy, and associated neurological problems were caused by the pertussis immunization, in the opinion of Drs. Drew and Wissman.

The patient was seen later at Riley Hospital at age ten months and at that time had follow-up CSF studies on March 3, 1976. These CSF studies do demonstrate some

nonspecific chronic inflammatory changes, but the previously noted demyelinating changes seen in the CSF studies of August 22, 1975, had resolved. The presence of the acute demyelinating changes at the time of the insult and later resolution of these changes is consistent with an acute and transient demyelinating central nervous system disturbance.

At the time the patient was initially hospitalized at Riley Children's Hospital in August, 1975, Dr. Drew made some comments regarding the use of immunizations in children especially children who might have some central nervous system disturbance. These comments which were mentioned in the discharge summary by Dr. Wissman should be considered generic comments regarding the problem of immunizing children with central nervous system isults and do not appear to directly reflect his management of Margaret Ann Whitecotton.

Should you have further questions regarding Ms. Whitecotton's clinical course or her laboratory studies, please feel free to contact me.

Sincerely yours,

/s/ Paul F. Bustion M.D.
PAUL F. BUSTION, M.D.
PFB/dge

CC: M.G. Whitecotton

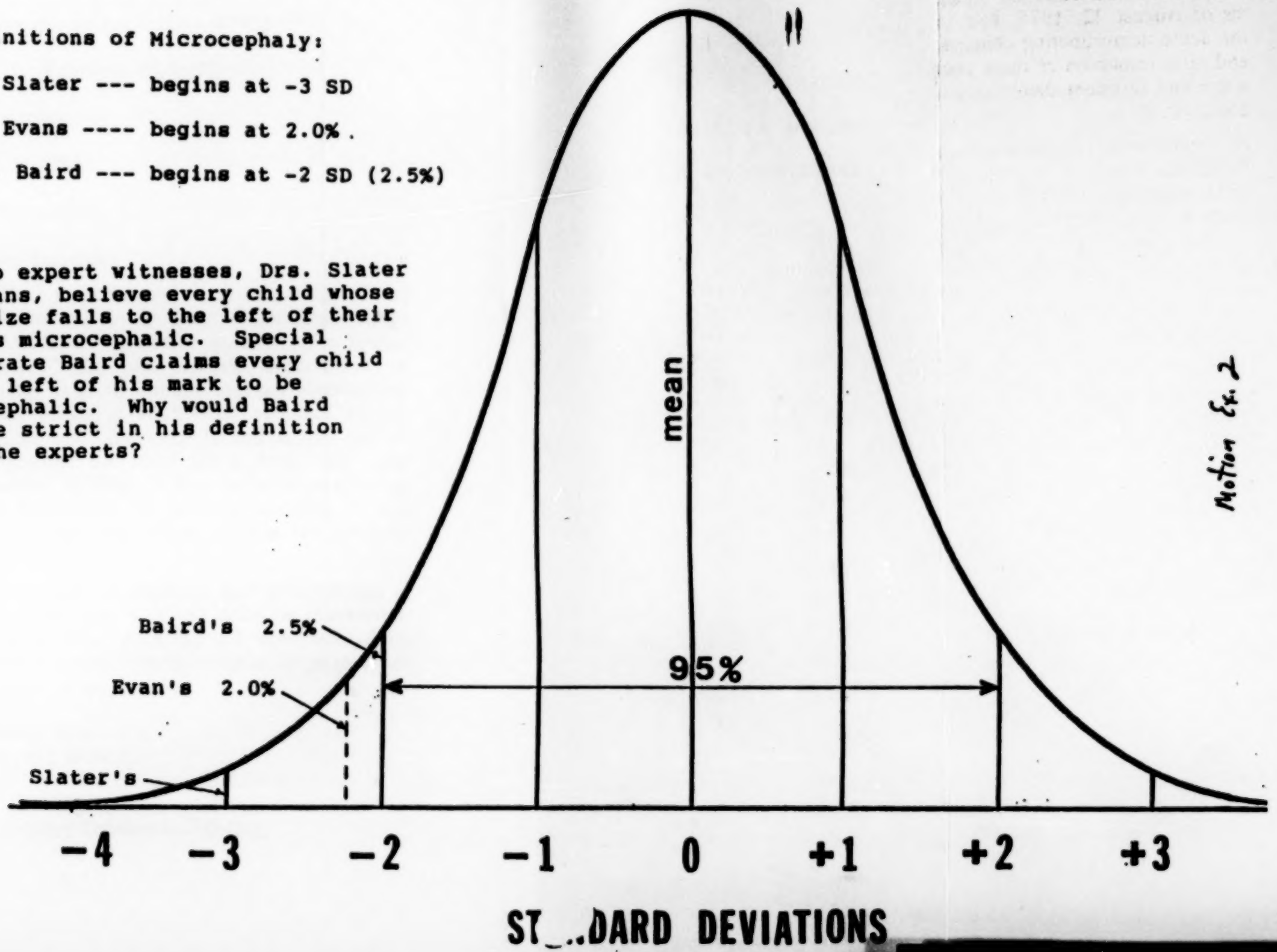
Definitions of Microcephaly:

Dr. Slater --- begins at -3 SD

Dr. Evans ---- begins at 2.0%.

S.M. Baird --- begins at -2 SD (2.5%)

The two expert witnesses, Drs. Slater and Evans, believe every child whose head size falls to the left of their mark is microcephalic. Special Magistrate Baird claims every child to the left of his mark to be microcephalic. Why would Baird be more strict in his definition than the experts?




Motion Ex. 2

M. KEITH BAIRD, M.D.
215 Ward Avenue
Crawfordsville, Indiana 47933

February 13, 1992

Mrs. Kay Whitecotton
13 Twin Oaks
Crawfordsville, IN 47933

Re: Maggie Whitecotton

To Whom It May Concern:

I have been asked to comment on the meaning of the statement "ENT-Normal" in my letter to Dr. Drew dated August 19, 1975. There was some question by a lawyer that "ENT-Normal" did not include observation of normal swallowing. It is my opinion that my observations did include observations of swallowing and that no abnormal swallowing was observed. Indeed in the second paragraph I "watched the child for a long time" and specifically observed sucking (which includes swallowing motion). Then I observed the sucking stopping. I specifically noted the gag reflex which involves the swallowing mechanisms.

The legal system tends to conclude that if something is not specifically stated that it wasn't done or observed—this is an erroneous view. After all if I wrote everything normal I observe I would have to write a 20 page chapter of an ENT book on each patient.

/s/ M. Keith Baird, M.D.
M. KEITH BAIRD, M.D.
MKB/dab
cc:file

[Notary Omitted in Printing]

**AFFIDAVIT**

I, Kay Whitecotton, being first duly sworn upon my oath, say that I am the mother of Margaret Whitecotton. At the time of the hearing before Special Master Baird that those statements were untrue and that she did not have and had not had swallowing problems since birth. That Special Master Baird made a finding that he considered the statement of Dr. D.S. Hwang, M.D. that she had had a swallowing problem since birth was credible. That in preparing for the appeal on this case, the undersigned became concerned about the statement made by Special Master Baird in his decision and on or about the latter part of February, 1992, I contacted Dr. Hwang about the statement he had made on August 28, 1979 that "she has had a swallowing problem since birth".

When I talked with Dr. Hwang the latter part of February, 1992, he advised that before he could answer any questions, he would have to review records. He reviewed all the records and advised me that she categorically had no swallowing problems since birth, as evidenced by his February 24, 1992 letter. That at the time of the hearing before the Special Master, I was not specifically aware of Dr. Hwang's statement in the multitude of medical records, but when questioned, I did rebut Dr. Hwang's statement. I did testify to this but Special Master Baird did not find my evidence credible as opposed to that of the Dr. Hwang. Specifically now, the letter of Dr. Hwang clearly indicates to the contrary making the conclusion drawn by Special Master Baird incorrect. I did not know that this specific evidence would come into play with regard to the Court's decision until the Court, in its decision, refused to believe my statement as the mother of Margaret Whitecotton. Therefore, I decided to contact Dr. Hwang and obtain this information on February 24, 1992. See attached letter from Dr. Hwang.

At the same time, I contacted M. Keith Baird, M.D. who was the treating physician who observed Maggie



having an adverse reaction to the DPT shot on August 19, 1975. I contacted him because there was a question or doubt by Special Master Baird and/or the government about Maggie having swallowing problems. Dr. Baird concluded that she had no abnormal swallowing problems. See his letter of February 13, 1992. This information was not available at the last hearing because I did not know that Special Master Baird or the government would try to re-interpret Dr. Baird's letter or mis-state his conclusions.

Further, that after the decision by the Special Master, I decided to gather additional information for my attorney in preparation of any appeal brief and asked my neighbor, Dr. Timothy Tanselle, to schedule an appointment for me with a neurologist in Indianapolis. He did schedule an appointment for me with Dr. Bustion of Hoosier Neurology. My husband and I went over to see him which resulted in a letter which was included in a motion for hearing before the Court dated September 11, 1991. At the time of that meeting, Dr. Bustion did not mention anything about being present when Maggie was diagnosed at Riley Hospital.

That on February 18, 1992, when I again met with Dr. Bustion and John S. Capper, IV, who desired to obtain information that might be helpful in the appeals case, he indicated for the first time that he was present when Dr. Drew made his diagnosis of Maggie, stating that she had suffered from post-immunization encephalopathy, or an adverse reaction to the DPT shot. This was quite shocking to me that someone else was present at the time Dr. Drew made his diagnosis and who is also in the field of neurology. That this person would be an excellent witness to further inform the Court as to Maggie's condition and her adverse reaction. That this person was not available and only through pure coincidence did I come to know about Dr. Bustion.

That after the Court's decision, I became so upset with the Court's interpretation that my daughter was micro-

cephalic since birth that even though the obstetrician's records who delivered her were in the record, I contacted him on March 12, 1992 and advised him that Special Master Baird and other medical experts were saying that my daughter was microcephalic since birth. Pursuant to the medical records already in the case and a most recent letter from him, Maggie has not been microcephalic since birth. See attached letter from Jack Foltz, M.D.

And further Affiant saith not.

/s/ Kay Whitecotton
KAY WHITECOTTON

[Notary Omitted in Printing]



HOOSIER NEUROLOGY, P.C.

[Adresses Omitted in Printing]

March 23, 1992

Mr. and Mrs. Michael Whitecotton
#13 Twin Oaks
Crawfordsville, Indiana 47933

Dear Mr. and Mrs. Whitecotton:

I am writing to you in regards to Margaret Ann Whitecotton, your daughter, and acknowledging that I met with Kay Whitecotton, her mother, and John S. Capper, IV, your attorney, on February 18, 1992 in my office. While reviewing Maggie's case and having reviewed the discharge summary from Riley Hospital of Indiana University Hospitals, dated August 20, 1975, I realized that that this case was familiar, and that I was present at Riley Hospital August 19, 1975 when Margaret Ann Whitecotton was a patient of Dr. Les Drew, her attending physician, at which time he made his diagnosis.

Although I had written a letter to John S. Capper, IV, your attorney, in September of 1991 regarding Margaret Whitecotton, I did not recall until my meeting of February 18, 1992, when reviewing medical information in detail that I had been present when Dr. Drew made his diagnosis of post immunization encephalopathy.

I now affirm, under oath, by way of this letter that Dr. Drew diagnosed Maggie Whitecotton as having an adverse reaction to a DPT shot, particularly, post immunization encephalopathy, with associated seizures. I specifically recall Dr. Drew explaining to us the encephalopathy, seizure disorder, and other neurological problems, as a consequence of the Pertusis immunization, in the opinion of Dr. Drew. Dr. Drew at the time was the head of the Pediatric Neurology Department at Riley Hospital. Dr.

Drew did not state nor did he consider her condition to be the result of microencephaly.

I acknowledge that I wrote a letter on September 11, 1991 to John S. Capper, IV, your attorney, discussing Maggie's condition, however, at the time, I did not realized that she was a patient that I had attended with Dr. Drew when she was diagnosed by Dr. Drew in 1975 with post immunization encephalopathy.

At the time of my conversation with Mrs. Whitecotton, and Mr. Capper I reviewed with them also the electroencephalography report of August 25, 1975, showing an EEG poorly organized and slightly slow for her age. I also reviewed an electroencephalogram dated September 29, 1975 that indicated the EEG was within normal limits. It is my medical opinion, based upon a reasonable degree of medical certainty and pursuant to the National Childhood Vaccine Injury Act, that the patient's condition was one of encephalopathy as defined in the National Childhood Vaccine Injury Act. The electroencephalogram reports collaborates this finding.

Sincerely yours,

/s/ Paul F. Bustion, M.D.
PAUL F. BUSTION, M.D.
PFB/dge



**Paul F. Bustion, M.D.**
**1801 North Senate Boulevard, Suite 510**
**Indianapolis, Indiana 46202**
**Phone: (317) 929-5910**

## CURRICULUM VITAE

| | |
|---|---|
| **Date of Birth:** | **September 1, 1949** |
| **Social Security #:** | **314-48-7962** |
| **Birthplace:** | **Victoria, Texas** |
| **Marital Status:** | **Married—Barbara K. Bustion (1975)** |
| **Dependents:** | **Two children** |
| **Home Address:** | **837 Forest Drive<br>Anderson, Indiana 46016** |
| **High School:** | **William Henry Harrison<br>Evansville, Indiana<br>1963-1967<br>Graduation—June 1967** |
| **Pre-Med:** | **St. John's College<br>Santa Fe, New Mexico<br>1967-1971<br>Graduation—June 1971<br>B.A. Degree** |
| **Medical School:** | **Indiana University School of Medicine<br>1971-1976<br>M.D.—June 1976** |
| **Internship:** | **Indiana University Hospitals<br>1976-1978<br>Pediatrics** |
| **Residency:** | **Indiana University Hospitals<br>1977-1978<br>Pediatrics** |
| **Residency:** | **Indiana University Hospitals<br>1978-1981<br>Neurology** |

| | |
|---|---|
| Medical License: | 1976—325578 |
| Military Service: | None |
| Teaching Appointments: | Indiana University<br>Department of Neurology<br>Clinical Professor of Neurology<br>1981-Present |
| Medical Societies: | American Academy of Neurology<br>1980-Present<br>Associate Member |
| | Indiana Neurological Society<br>1978-Present |
| | AMA, ISMA, Madison County Medical Society<br>1981-Present |
| | American Institute of Ultrasound in Medicine<br>1982-Present |
| CME: | Attached |
| References: | To be provided |
| Hospitals: | St. John's Hospital Medical Center<br>Anderson, Indiana |
| | Community Hospital of Anderson<br>Anderson, Indiana |
| | Methodist Hospital of Indiana<br>Indianapolis, Indiana |
| | Winona Memorial Hospital<br>Indianapolis, Indiana |
| | Johnson County Memorial Hospital<br>Franklin, Indiana |
| Malpractice: | Physician's Insurance Company of Indiana |



JACK L. FOLTZ, M.D.
Obstetrics & Gynecology
297 West Franciscan—Suite 201
Crown Point, Indiana 46307
(219) 862-1320

March 12, 1992

TO WHOM IT MAY CONCERN:

I was Kay Whitecotton's obstetrician for her delivery with Maggie. There was no problem with her pregnancy or delivery. Maggie was small but completely normal and not microcephalic.

Maggie had no problems until her episode following a DPT Vaccination. I feel that her neurological condition now is due to this unfortunate reaction and was not present before the Vaccination.

Sincerely,

/s/ Jack L. Foltz, M.D.
JACK L. FOLTZ, M.D.

[Notary Omitted in Printing]

[LOGO]

INDIANA UNIVERSITY
SCHOOL OF MEDICINE

Department of Orthopaedic Surgery
Section of Pediatric Orthopaedics
James Whitcomb Riley Hospital for Children 1101
702 Barnhill Drive
Indiana University Medical Center
Indianapolis, Indiana 46202-5215
(317) 274-5650

March 6, 1992

Re: Margaret Whitecotton

TO WHOM IT MAY CONCERN:

Maggie Whitecotton has been under my care for her orthopaedic problems since 1979. Maggie had dislocation of the hip secondary to muscle imbalance due to her cerebral palsy. She did not have a congenital dislocation of the hip.

If there are any further questions, feel free to contact my office directly.

Yours sincerely,

/s/ G. Paul DeRosa, M.D.
G. PAUL DEROSA, M.D.
Professor and Chairman
Department of Orthopaedic Surgery

GPD/smb

[Notary Omitted in Printing]



DO S. HWANG, M.D., F.A.A.P.
1704 North Lafayette Road
Crawfordsville, Indiana 47933

Telephone 362-5100

March 12, 1992

Patient: Margaret Ann Whitecotton

To Whom It May Concern:

Maggie's parents have asked me to review the accuracy of the statement "she has had a swallowing problem since birth" which appeared on a Culver Hospital record dated 8-28-79. I have researched my files and other physicians' files. Based upon my personal knowledge, Maggie had no swallowing problem at birth or at an early age.

The following things verify or support this statement:

1. I saw Maggie in my office four times prior to the hospital stay in question. The visits were from 7/19/77 thru 6/3/79. On Maggie's first visit, I noted her mother stated she was eating well. On the three following visits nothing was ever mentioned or observed during the examinations of a swallowing problem. If it had been mentioned or detected, I would have definitely noted it on her file.
2. Maggie had other doctors before 8-28-79 and my personal review of their notes show no swallowing problems.

a. 4-22-75 Admitting physician, J.M. Foltz M.D., stated no abnormalities, and the sucking and swallowing reflexes were normal.

b. 4-25-75 Discharging physician, W.E. Shannon M.D., stated no abnormalities, and the sucking and swallowing reflexes were normal.

c. 8-19-75 Associate family physician, M.K. Baird M.D., stated prior examinations had been normal. Ear, nose, and throat and the gag reflex exam was normal. I note the letter from Dr. Baird (2-13-92) clarifies his observation.

d. 8-20-75 Indiana University (Riley Hospital for Children) physician, S. Wissman M.D., stated in discharge summary that Maggie was sucking on pacifier and the ENT was normal. (Nurse noted that Maggie was eating solids well).

e. 2-24-76 Indiana University (Riley Hospital for Children) nurse's notes, stated mother fed the child solid foods. (There was no mention of swallowing problems throughout the report).

f. 1-16-77 Family physician, J.C. Shank M.D., lists her feeding as normal table food. (There is also no mention of a swallowing problem).

On 8-28-79 Maggie was brought to the emergency room with her mother in panic. Maggie was pale and limp. She had just experienced rolling eyes and loss of color. She had become still and didn't respond to her mother's stimulation. These are typical characteristics of a seizure (a seizure was recorded on the hospital record). Abnormal swallowing accompanies a seizure. Her records show that her first seizures and a dinosis of post-immunization encephalopathy occurred following her third DPT shot at the age of four months.

While conversing with a parent or a close friend, I must have noted something about the swallowing that commonly accompanies a seizure. It is also possible an error in the transcription may have occurred.



I can categorically state that, other than the 8-28-79 entry, there is not substantive backing in the records or reports of the previously listed doctors, that would indicate that Maggie had a swallowing problem at birth or an early age.

Sincerely,

/s/ D.S. Hwang, M.D.
D.S. Hwang, M.D. F.A.A.P.

[Notary Omitted in Printing]

IN THE UNITED STATES CLAIMS COURT
OFFICE OF THE SPECIAL MASTERS

(Filed: September 15, 1992)

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No. 90-692V

PUBLISH

MARGARET WHITECOTTON, by her next friends,
KAY WHITECOTTON AND MICHAEL WHITECOTTON,
PETITIONERS

*v.*

SECRETARY OF THE DEPT. OF
HEALTH AND HUMAN SERVICES, RESPONDENT

---

**ORDER**[1]

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*BAIRD, Special Master*

Procedural Background

On January 29, 1992, judgment was entered in the above-entitled matter denying the petitioners' claim for compensation under the National Vaccine Injury Compensation Program. On March 27, 1992, the petitioners filed a petition for review of the decision of the Claims Court in the United States Court of Appeals for the Federal Circuit. Three days after filing the appeal, the petitioners filed a motion in this court to set aside the

[1] Although the Order of Remand filed July 1, 1992 indicated that the undersigned should "submit a report . . . with . . . recommendation for disposition" of the motion, it also provided that the undersigned's "ruling on the motion" should be handled in all respects as a final decision. It is for that reason that the report is being issued in the form of an order. Review of this order may be obtained by filing a motion for review pursuant to 42 U.S.C.A. § 300aa-12(e) (West 1991) within 30 days.



judgment and for rehearing on their petition, pursuant to RUSCC 60(b), based on newly discovered evidence. A brief in response to the motion—urging that it be summarily rejected—was filed by the respondent on April 13, 1992. The motion was remanded by the court to the undersigned on July 1, 1992 for appropriate action. At a status conference held by the undersigned on July 23, 1992, petitioners requested and were granted leave to file an amended motion. The amended motion, with additional exhibits, was filed on August 25, 1992.[2] After reviewing the written filings, argument was deemed unnecessary.

This Court Has Authority To Deny The Motion
Without Seeking Remand

RUSCC 60(b) provides that "[o]n motion and upon such terms as are just, the court may relieve a party or the party's legal representative from a final judgment, order, or proceeding for the following reasons: . . . (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); . . . ."[3]

The respondent opposed the motion on two grounds: (1) that the filing of the appeal divested this court of jurisdiction to grant the motion; and (2) that the motion is without merit under Rule 60(b).

The court agrees with the respondent on both points. Under the holdings in *Placeway Construction Corp. v.* U.S., 19 Cl. Ct. 484 (1990), and *Yachts America, Inc.*

[2] The amended motion seeks to invoke RUSCC 59 as well as RUSCC 60(b), even though the original motion acknowledged that a motion under Rule 59 would be untimely. Because the petitioners failed to comply with the time requirements of RUSCC 59, the special master has applied the standard set out in RUSCC 60(b) in assessing the merits of the motion, as amended.

[3] A motion for a new trial under RUSCC 59(b) must be filed within ten days after the entry of judgment.

*v. U.S.*, 8 Cl. Ct. 278 (1985), *aff'd*, 779 F.2d 656 (Fed. Cir. 1985), *cert. denied*, 479 U.S. 832 (1986), which this court chooses to follow, once the appeal was filed, the Claims Court lost jurisdiction over the case except to act in aid of the appeal or to correct clerical errors. Under its authority to act in aid of the appeal, this court may deny a Rule 60(b) motion, but it does not have jurisdiction to grant such a motion. If it is inclined to grant the motion, it may inform the appellate court of its inclination and request remand, but it may not grant the motion unless the case is remanded by the appellate court.[4]

Relief Is Not Warranted Under RUSCC 60(b)

*Yachts America* provides the following guidance in determining whether to grant a Rule 60(b) motion:

> When seeking relief because of "newly discovered evidence," the party must show "(1) that the evidence was actually 'newly discovered'; that is, it must have been discovered subsequent to the trial; (2) that the movant exercised due diligence; and (3) that the evidence is material, not merely impeaching or cumulative, and that a new trial would probably produce a different result." (quoting *Warner v. Transamerica Insurance Co.*, 739 F.2d 1347, 1353 (8th Cir. 1984). . . .
>
> Newly discovered evidence is evidence of facts which existed at the time of decision and of which the aggrieved party was excusably ignorant. (citation omitted) To be excusably ignorant, of course, the party must have exercised due diligence in locating the evidence. And the evidence may not be merely cumulative; it must be such as would alter the outcome of the case. (citations omitted)

8 Cl. Ct. at 281.

[4] The wording of the stay order of the Federal Appeals for the Federal Circuit filed June 26, 1992, which provided that a motion for remand should be filed if this court indicated an inclination to grant the motion, is consistent with this analysis.



The court in *Placeway Construction Corp.* noted, further, that "a Rule 60(b) 'motion for relief from judgment is one for extraordinary relief entrusted to the discretion of the Court . . . which may be granted only in exceptional circumstances.'" 19 Cl. Ct. at 489 (quoting from *Sioux Tribe of Indians v. United States*, 14 Cl. Ct. 94, 101 (1987), *aff'd*, 862 F.2d 275 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1075 (1989)).

The respondent argues that the "newly discovered evidence" offered by the petitioners fails two of the three requirements set out in *Yachts America*: it could have been discovered by due diligence before the hearing, so petitioners were not excusably ignorant of it; and it would not be likely to produce a different result if it were part of the record. Although they do not apply equally to all of the proffered evidence, these arguments are well taken.

The first two items of evidence proffered deal with the issue of whether Maggie Whitecotton had a swallowing problem prior to receiving the DPT vaccine. The first, exhibit (hereinafter Ex.) AA [5], is a statement from a treating doctor, Do S. Hwang, M.D., indicating that he has reviewed Maggie's records and finds no support for an entry which appeared in his records to the effect that Maggie had had swallowing problems since birth. The petitioners were aware of that entry prior to the hearing—it appeared in documents filed by them—and they could have contacted Dr. Hwang concerning it be-

[5] The memorandum in support of the motion to set aside the judgment filed March 30, 1992 mistakenly refers to the exhibit as "CC." Such erroneous referencing appears consistently throughout the memorandum.

fore the hearing. This, then, does not qualify as newly discovered evidence. It is merely an effort to raise doubts about (*i.e.*, impeach) the validity of record evidence. The second, Ex. BB, is a letter from another treating physician, M. Keith Baird, M.D., indicating that when he included the observation "ENT-Normal" in a letter dated August 19, 1975, the observation included observations of swallowing. This, too, is merely a clarification of a record which could easily have been obtained prior to the hearing. More telling, though, for both of these items, is their insignificance. Counsel for petitioners should recognize that the decision of the special master did not turn on whether Maggie had swallowing problems from birth. The decision referred to the swallowing issue as only a "hint" that Maggie might have had preexisting neurologic complications, and went on to state that "there was little evidence of complications of microcephaly prior to August 18, 1975." Slip op. at 9, 10 (Cl. Ct. Spec. Mstr. Aug. 16, 1991). The proffered evidence on swallowing problems would not produce a different result.

The third proffered item of evidence, Ex. CC, is a letter from Paul F. Bustion, M.D., recalling what he was told by Dr. Les Drew concerning the cause of Maggie's encephalopathy, seizure disorder, and other neurological problems. While the evidence in this letter could probably not have been discovered by due diligence prior to the hearing, it is considered to be a less reliable indicator of what Dr. Drew's opinion was than the entries made in 1975 in Maggie's medical records. It is clear from those entries that Dr. Drew was of the opinion that Maggie was microcephalic and had preexisting brain damage and that he was concerned about further indications of "CNS dysfunction associated with microcephaly." Ex. F to petition at 1-2. The decision filed August 16, 1991 recognized that the treating physicians considered Maggie to have suffered an acute "postimmunization encephalopathy



with seizures." However, according to the records, Dr. Drew attributed her root problem to preexisting brain damage and microcephaly. Dr. Bustion's letter would not produce a different result.

The fourth proffered item, Ex. DD, is a statement from the doctor who delivered Maggie stating that she was not microcephalic at birth and opining that her present condition is due to an unfortunate reaction to the DPT vaccine. The opinion testimony clearly falls outside the realm of newly discovered evidence. The statement as to whether Maggie was microcephalic at birth does not change anything. The special master's decision found "that Maggie was at least borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot." Slip op. at 7. That finding is accurate based on medical standards for determining microcephaly, and nothing Dr. Foltz has said changes that. His statement would not produce a different result.

The final item filed with the original motion, Ex. EE, is a letter from G. Paul DeRosa, M.D., an orthopedic surgeon who has treated Maggie since 1979. Dr. DeRosa states that Maggie's hip dislocation was not congenital, but secondary to muscle imbalance due to her cerebral palsy. The decision noted that Maggie's medical records consistently refer to her hip dislocation as being congenital. The testimony of Dr. DeRosa, which is impeaching in character, is also evidence which could have been obtained prior to the hearing; but it doesn't matter in the context of this case whether Maggie's hip dislocation was congenital or secondary to her cerebral palsy because the court has found that her cerebral palsy is not vaccine-related.[6] Dr. DeRosa's letter does not speak to that issue and would not produce a different result.

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[6] This same point was made by Judge Turner in his Opinion and Order filed January 14, 1992, at n.6.

In the amended motion, the petitioners argue that there is newly discovered evidence which was not available and could not have been discovered prior to trial with due diligence which is likely to lead to a change in the original result. As evidence they offer excerpts from two medical treatises, Exs. HH and II, which, they assert, show that demyelination occurs in encephalopathies following DPT immunization.[7] No assertion is made that these sources were not available prior to the hearing. Rather, petitioners argue that their counsel was misled by the special master prior to the hearing into believing that they had established a Table case, so that he did not prepare the case as he would have had he thought he was going to have to prove that a Table injury occurred.

The petition alleged that an encephalopathy had occurred following the DPT vaccination, but made no allegation concerning a residual seizure order. At the initial status conference, the special master, pursuant to Vaccine Rule 5, provided the parties with his initial assessment of the case. That conference was off the record. The recollection of the special master is that he advised the parties that there was no clear evidence in the record of an encephalopathy following the vaccination and that there was some indication of a preexisting brain anomaly. He noted that Maggie had suffered multiple afebrile seizures on the day following the vaccination and that, if those were her first seizures, she would meet the threshold requirement for establishing a residual seizure disorder. He also noted that there was an indication in the record that she may have had earlier seizures and that that needed to be explored. The special master did not rule at that conference that the petitioners were entitled to an award based on a residual seizure disorder. Any such ruling would have been put in writing.

[7] Exhibit II does not even mention DPT vaccine.



The order issued following the initial status conference indicated that a hearing limited to the issue of entitlement would be held at a time yet to be determined. When such an order is issued, it indicates that no decision concerning entitlement has been made and that the special master has enough reservations about entitlement to bifurcate the entitlement and compensation portions of the case.

When the petitioners moved for summary judgment on the residual seizure disorder during their opening statement at the hearing, the motion was denied. The petitioners did not move for a continuance or make any claim that they had detrimentally relied on representations made by the special master in preparing their case for hearing. If they believed they had cause to complain, they should have done so then, not after judgment.

The raising of the question of demyelination in the amended motion is nothing more than an improper attempt to retry the issue of whether an encephalopathy occurred following the vaccination. There is no basis for concluding that there is *any* newly discovered evidence, let alone that it is evidence which could not have been discovered by due diligence prior to the hearing.

The petitioners have proffered nothing—whether considered individually or collectively—which would come close to producing a different result if it had been made part of the record at the hearing. Their motion is without merit under Rule 60(b) and is, therefore, DENIED.

/s/ Paul T. Baird
PAUL T. BAIRD
Special Master

IN THE UNITED STATES COURT
OF FEDERAL CLAIMS
January 7, 1993

No. 90-692V

MARGARET WHITECOTTON, by her next friends,
Kay Whitecotton and Michael Whitecotton, PETITIONER,

*versus*

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES, RESPONDENT.

[Filed Jan. 7, 1993]

John S. Capper, IV, Crawfordsville, Indiana, for petitioner.

Karen P. Hewitt, with whom were Assistant Attorney General Stuart M. Gerson, Helene M. Goldberg, John Lodge Euler and Charles R. Gross, Washington, D.C., for respondent.

**OPINION AND ORDER**

TURNER, Judge.

This action stands on petitioner's motion under RCFC 60(b) for relief from judgment based on newly discovered evidence. We conclude, based on the recommendation of the special master, that petitioner's motion should be denied.

I

In August 1990, Maggie Whitecotton filed a petition seeking compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10-300aa-34 (1988), *as amended* by several public laws codified in 42 U.S.C.A. §§ 300aa-10—300aa-34 (West Supp. 1991) (Vaccine Act), for injuries allegedly suffered as a result



of a diphtheria-pertussis-tetanus (DPT) vaccination. After conducting an evidentiary hearing, the special master issued a decision denying compensation. We sustained the special master's decision in an opinion dated January 14, 1992, and judgment for the respondent was entered on January 29, 1992.

On March 27, 1992, petitioner appealed the decision to the United States Court of Appeals for the Federal Circuit, and three days later, on March 30, 1992, petitioner filed a motion under RCFC 60(b) for relief from judgment based on newly discovered evidence. The Federal Circuit stayed the proceedings pending resolution of the Rule 60(b) motion by the Court of Federal Claims.[1] On July 1, 1992, we referred the case to the special master for proceedings to assist in the resolution of the Rule 60(b) motion. In a September 15, 1992 report, the special master recommended that the motion for relief from judgment be denied.[2] Petitioner responded by filing

[1] In granting petitioner's motion to stay the proceedings, Judge Rader stated:

> It is the usual practice of this court to stay proceedings pending a trial court's ruling on a 60(b) motion. If the motion is denied, any appeal should be promptly filed and consolidated with the underlying appeal. If the trial court indicates that it is inclined to grant such a motion, then a motion to remand should be promptly filed.

Order of the Court of Appeals, Rader, Circuit Judge (June 25, 1992).

[2] The special master, who issued his recommendation in the form of an order, noted his confusion with the Order of Remand as follows:

> Although the Order of Remand filed July 1, 1992 indicated that the undersigned should "submi[t] a report . . . with . . . recommendation for disposition" of the motion, it also provided that the undersigned's "ruling on the motion" should be handled in all respects as a final decision. It is for that reason that the report is being issued in the form of an order. Review of this order may be obtained by filing a motion for re-

a "motion for review" of the special master's report. Familiarity with the orders previously issued in this case is assumed.

II

Petitioner seeks relief from judgment under Rule 60(b) due to newly discovered evidence.[3] Under Rule 60(b)(2), the court may relieve a party from a final judgment if there is "newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b)."[4] A motion for relief from judgment under Rule 60(b) may be granted only in exceptional circumstances. *See Washington Medical Center, Inc. v. United States*, 211 Ct. Cl. 379, 379-80 (1977); *Sioux Tribe of Indians v. United States*, 14 Cl. Ct. 94, 101 (1987), *aff'd* 862 F.2d 275 (Fed. Cir. 1988),

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view pursuant to 42 U.S.C.A. § 300aa-12(e) (West 1991) within 30 days.

Order of Special Master, No. 90-692, slip op. at 1 n.1 (September 15, 1992).

Because we did not intend for the special master to issue a "final decision" but instead to make a "recommendation for disposition," we will treat the special master's report as merely a "recommendation." As such, we will not apply the exacting standard of review embodied in 42 U.S.C.A. § 300aa-12(e)(2). Instead, we consider petitioner's motion in the first instance.

[3] A substantial portion of petitioner's motion for review objects to legal rulings in this court's original decision. None of the objections relating to this court's original decision in this case should be revisited under Rule 60(b). That decision is already the subject of an appeal to the Federal Circuit, and each of the alleged errors in this court's original decision may be properly considered by the appellate court. *See Pierce v. UMW*, 770 F.2d 449, 451 (6th Cir. 1985), *cert. denied*, 474 U.S. 1104 (1986) (holding that a claim of legal error is not a basis for relief under Federal Rule of Civil Procedure 60(b)); *Martinez-McBean v. Virgin Islands*, 562 F.2d 908, 911 (3rd Cir. 1977) (same).

[4] A motion under RCFC 59(b) must be filed within ten days after the entry of judgment.



*cert. denied*, 490 U.S. 1075 (1989). When seeking relief under Rule 60(b), a party must show:

> (1) that the evidence was actually "newly discovered"; that is, it must have been discovered subsequent to the trial; (2) that the movant exercised due diligence; and (3) that the evidence is material, not merely impeaching or cumulative, and that a new trial would probably produce a different result.

*Yachts America, Inc. v. United States*, 8 Cl. Ct. 278, 281, *aff'd* 779 F.2d 656 (Fed. Cir. 1985), (quoting *Warner v. Transamerica Insurance Co.*, 739 F.2d 1347, 1353 (8th Cir. 1984)).

Petitioner's alleged newly discovered evidence consists of five affidavits from physicians and two excerpts from medical treatises. *See* Petitioner's Exhibits AA-EE, HH & II.[5] We will discuss the substance of these items seriatim and then will address whether any of these items constitute "newly discovered evidence."

A

Two of the affidavits pertain to the issue of whether Maggie had a swallowing problem before she received the vaccine.

Exhibit AA is the affidavit of Dr. Hwang who was Maggie's treating physician at the time of her 1979 hospitalization. In his affidavit, Dr. Hwang asserts that based upon his personal knowledge and his review of other doctors' notes, Maggie did not have a swallowing problem before she received the vaccine. Petitioner submitted this affidavit because an entry appeared in Dr. Hwang's medical records concerning Maggie that said that she "has had difficulty swallowing since birth." Petitioner's Exhibit H-

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[5] Exhibits FF, GG and JJ were also submitted as part of petitioner's motion, but these exhibits constitute affidavits that were submitted to justify the post-judgment discovery of the evidence, not as examples of newly discovered evidence.

12. The special master relied on exhibit H-12 as evidence of a "hint" that Maggie may have had neurological complications before the vaccine was administered. SMD at 9.

Exhibit BB is the affidavit of Dr. Baird, a family physician who performed an ear, nose and throat examination on Maggie in 1975. In an August 19, 1975 letter to another physician, Dr. Baird indicated that Maggie was "ENT-Normal." In his affidavit, Dr. Baird states that his examination of Maggie included an observation of normal swallowing.

Two of the affidavits pertain to the issue of whether Maggie was microcephalic before the vaccine was administered.

Exhibit CC is the affidavit of Dr. Bustion, a consulting physician who was present during Maggie's August 1975 hospitalization. At the conclusion of Maggie's hospitalization, treating physicians prepared a written discharge diagnosis which said, in part:

> Discharge Diagnosis: (1) Microcephaly (2) Postimmunization encephalopathy with seizures.
>
> . . .
>
> DISPOSITION: It was thought that the patient's seizures were most likely secondary to the pertussis vaccine which she had received earlier in the day. It was Dr. Drew's feeling that children with microcephaly and some brain damage were unusually susceptible to this vaccine. It was decided to not start this child on any anticonvulsive medications at this time. The child will be followed by Dr. Drew in his office for any further seizure difficulty or any other evidence of CNS dysfunction associated with the microcephaly.

PX F. In his decision denying compensation, the special master relied on this statement:

> It is reasonable to infer from the discharge diagnosis and this statement that at least some of the treating physicians (1) considered Maggie to be microcephalic; (2) thought that she might have preexisting brain damage; (3) considered her seizures to have been immediately secondary to the DPT vaccine but ultimately evidence of CNS dysfunction associated with microcephaly; (4) thought that her seizures might prove to be transient; and (5) were more concerned about her microcephaly—than about the post-immunization encephalopathy—as a potential cause of further CNS dysfunction.



SMD at 5. Dr. Bustion's affidavit states that he was present when Maggie was diagnosed, that Maggie was diagnosed as having an adverse reaction to the DPT shot and that treating physicians did not consider her condition to be the result of microcephaly.

Exhibit DD is the affidavit of Kay Whitecotton's obstetrician, Dr. Foltz, and concerns Maggie's condition at birth. In his affidavit, Dr. Foltz asserts that "Maggie was small but completely normal and not microcephalic." Petitioner submitted this affidavit to contradict the special master's finding "that Maggie was at least borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot." SMD at 7.

Exhibit EE is the affidavit of Dr. DeRosa, Maggie's orthopedist, and concerns her dislocated hip. In his affidavit, Dr. DeRosa asserts that Maggie's hip dislocation was not congenital, but secondary to muscle imbalance due to her cerebral palsy. Petitioner submits this affidavit to contradict the special master's finding that Maggie's hip dislocation was congenital. SMD at 10-11.

The final two items (exhibits HH & II) consist of excerpts from two medical treatises.[6] The discharge statement from petitioner's 1975 hospitalization stated that

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[6] Exhibit HH is taken from Menkes, *Textbook on Child Neurology*. Exhibit II is taken from Evans, *Manual on Child Neurology*.

extracted spinal fluid revealed evidence of a subacute central nervous system affliction with a demyelinating component. Petitioner's Exhibit F. These two treatises are offered to show that demyelination occurs in encephalopathies following DPT vaccinations.

B

The special master reviewed each of the exhibits discussed in part IIA and found that each piece of evidence either could have been discovered had petitioner used due diligence or would not materially affect the outcome of the case. Therefore, the special master determined that the evidence did not satisfy the criteria for relief under Rule 60(b)(2). We agree with the recommendation of the special master.

With the exception of Dr. Bustion, each of the doctors submitting affidavits were treating physicians who were known to petitioner prior to the evidentiary hearing. The common characteristic of each of these affidavits is that they contain information that could have been discovered by petitioner if she had used due diligence in preparing for the evidentiary hearing. The statements from each of these doctors were within the reach of the petitioner. There is no satisfactory explanation offered for petitioner's failure to include the observations now offered when her case was initially presented.

Dr. Bustion never treated Maggie and therefore was not mentioned in any of her medical records. Apparently after judgment was entered in this case, petitioner discovered that Dr. Bustion was present when Maggie was diagnosed during her 1975 hospitalization. Even if it is assumed that this evidence could not have been discovered earlier if petitioner had used due diligence, the special master, in his recommendation to this court, said that he did not consider Dr. Bustion's affidavit to be more credible than the contemporaneously written discharge diagnosis that it contradicts. This affidavit falls within the category



of evidence that merely impeaches evidence in the record but does not affect the result, and we agree with the special master that the written diagnosis itself is more credible than the more recent statements of Dr. Bustion.

Finally, exhibits HH and II do not constitute newly discovered evidence because the evidence is cumulative of evidence already in the record. Petitioner's expert, Dr. Kitts, testified that there is a demyelinating component in DPT reactions, Tr. at 128; that is exactly what petitioner attempts to show with exhibits HH and II.

Accordingly, we conclude that petitioner's motion for relief from judgment should be denied because each item proffered either is cumulative of evidence already in the record or fails the "due diligence" test.

III

Based on the foregoing, petitioner's motion under RCFC 60(b)(2) for relief from judgment is DENIED.

/s/ James T. Turner
JAMES T. TURNER
Judge

SUPREME COURT OF THE UNITED STATES

---

No. 94-372

DONNA E. SHALALA, Secretary of Health and Human Services, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

---

**ORDER ALLOWING CERTIORARI**

Filed October 31, 1994

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The petition herein for a writ of certiorari to the United States Court of Appeals for the Federal Circuit is granted.

October 31, 1994

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No. 94-372

# In the Supreme Court of the United States

OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

## BRIEF FOR THE PETITIONER

DREW S. DAYS, III
*Solicitor General*

FRANK W. HUNGER
*Assistant Attorney General*

EDWIN S. KNEEDLER
*Deputy Solicitor General*

IRVING L. GORNSTEIN
*Assistant to the Solicitor General*

BARBARA C. BIDDLE
RICHARD A. OLDERMAN
KAREN P. HEWITT
*Attorneys*

*Department of Justice*
*Washington, D.C. 20530*
*(202) 514-2217*

## QUESTIONS PRESENTED

1. Whether, under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-11(c)(1)(C)(i), a presumption that a vaccine has caused an injury can be established by evidence that a symptom of the injury occurred shortly after administration of the vaccine, when that injury had already manifested itself prior to administration of the vaccine and the injury did not markedly worsen afterwards.

2. If so, whether the presumption of causation can be rebutted by a showing that an identifiable preexisting condition caused the injury, when the specific cause of that condition is unknown.

## PARTIES TO THE PROCEEDING

Petitioner is Donna E. Shalala, the Secretary of Health and Human Services. Respondents are Margaret, Kay and Michael Whitecotton.

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# In the Supreme Court of the United States

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DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

## BRIEF FOR THE PETITIONER

### OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-9a) is reported at 17 F.3d 374. The opinion of the United States Claims Court (now the Court of Federal Claims) (Pet. App. 10a-23a) and the decision of the Special Master (Pet. App. 24a-43a) are unreported.

### JURISDICTION

The judgment of the court of appeals was entered on February 15, 1994. A petition for rehearing was denied on April 29, 1994. Pet. App. 44a-45a. On July 19, 1994, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 27, 1994 (a Saturday). The petition for a writ of

certiorari was filed on August 29, 1994, and was granted on October 31, 1994. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

**STATUTORY PROVISIONS INVOLVED**

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992), provides, in pertinent part:

§ 300aa-11. Petitions for compensation

* * * * *

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died —

* * * * *

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table[.] * * *

* * * * *



§ 300aa-13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition; and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma

and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

* * * * *

§ 300aa-14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I. DPT * * *

| Illness, disability, injury, or condition covered: | Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration: |
|---|---|

* * * * *

B. Encephalopathy (or encephalitis) ..... 3 days

* * * * *



(b) Qualifications and aids to interpretation

* * * * *

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a) of this section:

* * * * *

(3) (A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa-11 of this title for a vaccine-

related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

* * * * *

§ 300aa-33. Definitions

For purposes of this part:

* * * * *

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

* * * * *

**STATEMENT**

1. In 1986, Congress enacted the National Childhood Vaccine Injury Act (Vaccine Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755, codified as amended at 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992). Part 1 of the Act directs the Secretary of Health and Human Services (Secretary) to establish a National Vaccine Program designed "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1; see 42 U.S.C. 300aa-1 to



300aa-6 (1988 & Supp. IV 1992). Part 2 of the Act, at issue here, establishes a National Vaccine Injury Compensation Program (compensation program), administered by the Secretary, "under which compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 42 U.S.C. 300aa-10 to 300aa-34 (1988 & Supp. IV 1992).

a. Under the compensation program, compensation for injury or death related to administration of a vaccine prior to the effective date of the Act in 1986 is paid out of appropriations by Congress. 42 U.S.C. 300aa-15(i)(1). Compensation in connection with administration of a vaccine after that date is paid out of the Vaccine Injury Compensation Trust Fund established in the Treasury by 26 U.S.C. 9510 (1988 & Supp. V 1993) and funded by a tax imposed by 26 U.S.C. 4131 on the manufacture of vaccines. See 42 U.S.C. 300aa-15(i)(2); see also 42 U.S.C. 300aa-15 (setting forth elements of compensation available under the program).

The compensation program is designed to afford a fair, informal, and expeditious alternative to tort suits against vaccine manufacturers as a way of securing a monetary recovery on behalf of persons who are alleged to have been injured by the administration of a vaccine. *Schafer* v. *American Cyanamid Co.*, 20 F. 3d 1, 2-3 (1st Cir. 1994); see, *e.g.*, 42 U.S.C. 300aa-12 (1988 & Supp. IV 1992) (describing procedures). Accordingly, in the case of a vaccine administered after the effective date of the Act, no civil action seeking more than $1000 in damages may be brought unless and until the claimant has exhausted the procedures under the Act. 42 U.S.C. 300aa-11(a)(2) (Supp. IV 1992); see also 42 U.S.C. 300aa-16 (1988 & Supp. IV 1992) (limitations of actions); 42 U.S.C. 300aa-21(a) (1988 & Supp. IV 1992) (election by claimant after procedures exhausted). The Act also provides

measures to encourage invocation of the compensation program in connection with claims based on administration of vaccines prior to the effective date of the Act. See, *e.g.*, 42 U.S.C. 300aa-10(b) (declaring it to be ethical obligation of attorney who is consulted about vaccine-related injury to advise individual that compensation may be available under the program); 42 U.S.C. 300aa-10(c) (Supp. IV 1992) (Secretary shall undertake reasonable efforts to inform the public of the availability of the program).

b. A proceeding under the compensation program is initiated by the filing of a petition in the Court of Federal Claims. 42 U.S.C. 300aa-11(a)(1) (Supp. IV 1992). A claimant may establish an entitlement to compensation by relying on the Vaccine Injury Table, which in effect provides for a rebuttable presumption of causation in certain circumstances. See 42 U.S.C. 300aa-14(a) (Supp. IV 1992). The Table identifies vaccines covered by the Act and lists particular injuries, disabilities, illnesses, and conditions after each vaccine. The Table then specifies for each injury, disability, illness, or condition a "[t]ime period for first symptom or manifestation of onset or of significant aggravation after vaccine administration." 42 U.S.C. 300aa-14(a) (Supp. IV 1992).[1] See p. 4, *supra*. The claimant is entitled to a rebuttable presumption of causation if the special master or court finds on the record as a whole that the claimant has shown by a preponderance of the evidence that a child "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine [the child received] * * *, and the first symptom or manifestation

[1] The Secretary has authority to promulgate regulations to modify the Vaccine Injury Table. See 42 U.S.C. 300aa-14(c).



of the onset or of the significant aggravation of any such illness, disability, injury, or condition * * * occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." 42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1) (A) (1988 & Supp. IV 1992).

The Secretary may rebut the presumption of causation and defeat the claim for compensation if she shows by a preponderance of the evidence that the illness, disability, injury, or condition "is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. 300aa-13(a)(1)(B) (1988 & Supp. IV 1992). The term "factors unrelated to the administration of the vaccine" does not, however, include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. 300aa-13(a)(2)(A).

If a child suffers from an injury that is not listed in the Table—or if the child suffers from an injury listed in the Table, but the first symptom or manifestation of the injury did not occur within the Table's time limits—recovery is not altogether precluded. Rather, in those circumstances, the claimant must prove that the vaccine caused the child's condition without the benefit of a rebuttable presumption. 42 U.S.C. 300aa-11(c)(1)(C)(ii).

c. Cases under the compensation program are adjudicated, in the first instance, by a special master. 42 U.S.C. 300aa-12(d)(3) (Supp. IV 1992). On motion by a party, the Court of Federal Claims will review the special master's decision. The court may either uphold the decision, or "set aside any findings of fact or conclusion of law * * * found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. 300aa-12(e)(2)(B)

(Supp. IV 1992). The decision of the Court of Federal Claims is subject to review in the United States Court of Appeals for the Federal Circuit. 42 U.S.C. 300aa-12(f) (Supp. IV 1992).

After judgment is entered by the Court of Federal Claims (or, if an appeal is taken, after the appellate court's mandate is issued), the petitioner who filed the petition under Section 300aa-11 must, within 90 days, file an election in writing with the clerk of the Court of Federal Claims to accept the judgment awarding or denying compensation, or to file a civil action for damages for the injury or death. If an election is not filed within 90 days, the petitioner is deemed to have accepted the judgment. 42 U.S.C. 300aa-21(a) (1988 & Supp. IV 1992).[2]

2. Respondent Margaret (Maggie) Whitecotton was born on April 22, 1975, with a head size in the second percentile, more than two standard deviations below the norm for a child of the same sex and age. Pet. App. 32a-33a. Maggie's head size remained at the second percentile through her first three months of age, but then fell below the second percentile. *Id.* at 33a-34a. The head size of a child is "indicative of the size of the brain." *Id.* at 33a. Children with particularly small heads have a condition known as microcephaly, which is most commonly defined as a head size two standard deviations below the norm for a child of the same sex and age. *Id.* at 32a.

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[2] The Act also prescribes standards of responsibility for manufacturers in any civil action filed with respect to administration of a vaccine after the effective date of the Act, 42 U.S.C. 300aa-22, and prescribes stages for the conduct of the trial in such a civil action and limitations on the availability of punitive damages, 42 U.S.C. 300aa-23 (1988 & Supp. IV 1992).



On August 18, 1975, when Maggie was nearly four months old, she received her third DPT vaccination. After administration of the vaccine, Maggie suffered a series of brief seizures. Pet. App. 27a. She was hospitalized, but subsequently discharged after a neurological examination indicated that her condition was normal and that she had suffered no apparent ill effects from the seizures. *Id.* at 40a. Her treating physicians also decided not to administer any anticonvulsive medication. *Id.* at 30a. The discharge summary diagnosed Maggie as having microcephaly and as having experienced postimmunization encephalopathy with seizures. *Ibid.* The discharge summary also noted the opinion of one treating physician that "children with microcephaly and some brain damage [are] unusually susceptible to this vaccine." *Ibid.*

There was no dramatic change in Maggie's condition following her release. Symptoms of neurological damage gradually appeared, however. Pet. App. 41a-42a. Currently, Maggie is "severely disabled both mentally and physically." *Id.* at 37a. She has cerebral palsy, hip and joint problems, and cannot communicate verbally. *Ibid.* She is, "for all practical purposes, totally dependent on others for her needs." *Ibid.* Maggie had several seizures in the five years following her third DPT vaccination, but has not had any seizures in recent years. *Id.* at 28a-30a.

3. On August 2, 1990, Maggie's parents, who are also respondents, applied for compensation under the Vaccine Act. Pet. App. 2a. They alleged that Maggie had suffered an "encephalopathy" as a result of her third DPT vaccination. *Ibid.* As noted above, an encephalopathy is one of the injuries listed in the Table in connection with the DPT vaccine. "Encephalopathy" is defined as "any significant acquired abnormality of, or injury to, or

impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A). To trigger the presumption of causation under the Table, the first symptom or manifestation of the onset or significant aggravation of an encephalopathy must occur within three days of the administration of the vaccine. 42 U.S.C. 300aa-14(a) (Supp. IV 1992). Maggie's parents alleged that Maggie's post-vaccination seizures were such a manifestation.

a. A special master denied compensation. Pet. App. 24a-43a. The special master adopted the most commonly accepted definition of microcephaly, namely a head size smaller than two standard deviations below the mean for a child of the same sex and age. By that definition, the special master concluded, a child whose head size is at the second percentile is microcephalic, "since the cutoff for two standard deviations is above the second percentile." Pet. App. 32a; see also *id.* at 20a (Claims Court decision). In this case, the special master noted that Maggie's head size was at the second percentile at birth and remained on the second percentile curve through three months of age, but had dropped below that curve by August 20, when she was examined in the hospital after the vaccine was administered. *Id.* at 33a. Based on that evidence, the special master found "that Maggie was at least borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot on August 18, 1975." *Id.* at 32a-33a.

The special master was persuaded by the evidence concerning Maggie's head size and the testimony of neurologists that "Maggie had suffered an encephalopathy sometime prior to the administration of the DPT vaccine on August 18, 1975." Pet. App. 33a. He cited the testimony of the government's expert, who believed that Maggie's head size indicated that she suffered brain injury prior to birth. *Id.* at 34a. The special master also



relied on respondents' expert, who testified that "[s]omething was clearly happening to the child before [the DPT vaccination]" (*id.* at 33a), and who stated in his report that the growth of Maggie's head had fallen below the normal curve, which "implie[d] a post-partum injury to the brain, at or near three months of age" (*id.* at 34a). On that record, the special master found that "[w]hether the injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975." *Ibid.* The special master therefore concluded that Maggie's "original encephalopathy was not a Table injury which followed the August 18 DPT shot." *Ibid.*

The special master also determined that the seizures that had occurred within the three-day statutory period after administration of the vaccine did not significantly aggravate Maggie's preexisting encephalopathy. Pet. App. 34a-43a. The special master found that in Maggie's early months, there were only hints, apart from her small head size, that she might have suffered brain damage. *Id.* at 36a. She rolled over from her stomach to her back at two weeks of age, which could be a sign of spasticity, and she had difficulty swallowing from birth, which could be a sign of mental retardation and cerebral palsy. *Id.* at 36a-37a. The special master found, however, that the absence of obvious symptoms of neurological damage in the early months of life was not atypical for a child with microcephaly. He noted that neurological problems often do not become obvious until a child matures to the point where developmental milestones (such as walking or talking) are missed or delayed. *Id.* at 37a. For example, cerebral palsy typically becomes evident between six months and one year of age. *Id.* at 38a. Mental retardation may not become evident until much later. *Ibid.* The special master determined that

there was more than a 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone. *Ibid.*

The special master further found that the DPT vaccination "may have caused a temporary encephalopathy evidenced by transient seizure activity, but the seizures did not continue and there was no dramatic turn for the worse in [Maggie's] condition indicating a permanent aggravation of her brain disorder." Pet. App. 42a. Rather, the special master explained, as Maggie "matured neurologically, the complications of whatever caused her microcephaly gradually manifested themselves, just as they do in a typical case involving congenital brain damage." *Ibid.* Accordingly, the special master found "no basis for implicating the vaccine as the cause of any aspect of [Maggie's] present condition." *Id.* at 42a-43a.

The special master issued formal findings of fact that were consistent with his analysis of the record evidence. Thus, the special master found that Maggie "was born * * * with a brain disorder evidenced by microcephaly which became more pronounced by the age of four months," that she "suffered transient seizure activity within three days following the administration of the DPT vaccine," that she "did not suffer a permanent encephalopathy within three days following the said administration of DPT vaccine," and that "[n]o significant aggravation of Maggie's underlying brain disorder was manifested within three days following the said administration of the DPT vaccine." Pet. App. 43a.[3]

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[3] Although respondents' petition for compensation alleged that Maggie suffered from an encephalopathy, respondents asserted at the hearing that Maggie also suffered from a residual seizure disorder. Pet. App. 26a n.2. The special master found that Maggie did not suffer from such a disorder, *id.* at 27a-30a, 42a, and the Claims Court sustained that finding, *id.* at 16a-19a. The court of appeals did not address that issue, and it is not involved here.



b. The United States Claims Court (now the Court of Federal Claims) overruled respondents' objections to the special master's decision and entered judgment for the Secretary. Pet. App. 10a-23a. The court concluded that there was sufficient evidence to support the special master's finding that Maggie was microcephalic before she received her third DPT vaccination, *id.* at 19a-21a, noting that "Maggie's preexisting injury precluded the vaccination from being the cause of the encephalopathy," *id.* at 21a. The court also found sufficient evidence to support the special master's finding that the seizures that had occurred within the three-day statutory period after administration of the vaccine were not an indication that the preexisting encephalopathy had been significantly aggravated by the vaccine. *Id.* at 23a. The court pointed out that "[t]here is simply no evidence that these transient seizures were a sign of permanent brain damage." *Ibid.* The court also cited evidence indicating that Maggie's "entire clinical history is typical for a person with a condition similar to [Maggie's] who did not have vaccine complications." *Ibid.*

c. The court of appeals reversed the judgment of the Claims Court and remanded for an award of compensation. Pet. App. 1a-9a. The court of appeals held that respondents' showing that Maggie had suffered seizures within three days following administration of the vaccine was sufficient to establish a presumption that the vaccine had caused the onset of an encephalopathy. *Id.* at 5a-7a. The court recognized that 42 U.S.C. 300aa-11(c)(1)(C)(i) requires a claimant to show that the first manifestation of any injury occurred after

administration of the vaccine. *Id.* at 5a. The court reasoned, however, that "the Table language [in 42 U.S.C. 300aa-14(a)] is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur." *Id.* at 5a.

The court then held that the Secretary could not rely on Maggie's preexisting microcephaly to show that her current condition was caused by a "factor unrelated" to the vaccine. Pet. App. 7a-8a. The court did not disturb the special master's findings that Maggie "was microcephalic before she received the suspect vaccine," and that her "microcephaly marked [her] as a child likely to experience developmental problems." *Id.* at 8a. And the court acknowledged that, "[l]ogically, these findings point to some preexisting condition, and not the vaccine, as the source of Maggie's injury." *Ibid.* Nonetheless, the court held that Maggie's microcephaly was not a "factor unrelated" to administration of the vaccine within the meaning of the Vaccine Act. *Id.* at 6a. Relying on its decision in *Koston* v. *Secretary, Dep't of HHS*, 974 F.2d 157, 160-161 (Fed. Cir. 1992), the court concluded that Maggie's microcephaly was "idiopathic" because, although it was preexisting, its specific cause could not be identified. Pet. App. 7a-8a.[4]

[4] The court of appeals denied the Secretary's petition for rehearing and suggestion for rehearing en banc. Pet. App. 44a-45a.



## SUMMARY OF ARGUMENT

The court of appeals has interpreted the Vaccine Act to require compensation in circumstances in which a child's condition logically could not have been caused by a vaccine. The court arrived at that result by misinterpreting two provisions of the Act.

A. First, the court erred in its construction of 42 U.S.C. 300aa-11(c)(1)(C)(i), which creates a presumption of causation when a claimant can show that "the first symptom or manifestation of the onset or of the significant aggravation" of the child's condition occurred within the time period after administration of the vaccine set forth in the Act. The court held that the phrase "first symptom or manifestation of the onset" means that a claimant is entitled to a presumption of causation as long as *any* symptom or manifestation of an underlying injury or condition occurred within the statutory period. In the court's view, the claimant does not have to show that there was no preexisting symptom or manifestation of that condition.

That construction is at odds with the plain meaning of the statutory text. When an injury or condition has manifested itself prior to administration of the vaccine, a manifestation after administration cannot be the "first." And when an injury or condition had its start prior to administration of the vaccine, any manifestation that occurs after that time cannot be a manifestation of the "onset."

The court of appeals' interpretation also renders superfluous the statutory text creating a presumption of causation when the first symptom or manifestation of a "significant aggravation" of a preexisting condition occurs within the statutory period after administration of the vaccine. If a presumption of causation arises

whenever any symptom happens to occur within the Table period, there would never be a need for a claimant to establish a significant aggravation of a preexisting condition. Implicit in Congress's decision to authorize significant aggravation as a separate ground for recovery is that there cannot be a presumption of causation when a condition that manifested itself prior to administration of the vaccine did not get markedly worse afterwards.

This interpretation of the statutory scheme also is the most logical. Presumptions are generally created when there is at least some likelihood that the presumption is in fact accurate. When a condition for which a claimant seeks recovery had already manifested itself prior to administration of the vaccine and the condition did not markedly worsen afterwards, there is no realistic possibility that the vaccine caused the condition.

The court of appeals, while recognizing that the language in Section 300aa-11(c)(1)(C)(i) did not support its interpretation of the Act, held that the language in the heading to the Table in 42 U.S.C. 300aa-14(a) (Supp. IV 1992) did. There is, however, no relevant distinction between the two Sections. Both provide that the symptom or manifestation in the statutory period must be "the *first* symptom or manifestation of the *onset* or of the significant aggravation" of the condition (emphasis added). Moreover, if there were a difference between the two, Section 300aa-11(c)(1)(C)(i) would take precedence, since that Section formally sets forth the elements that a claimant must establish. The language in Section 300aa-14(a) relied upon by the court of appeals is simply a heading that summarizes the requirements for a presumption in shorthand form. The other statutory provisions relied upon by the court of appeals merely articulate the details of the statutory scheme or fashion



special standards for its application in particular circumstances; they do not undermine the clear import of Section 300aa-11(c)(1)(C)(i).

B. The court of appeals also erred in holding that the Secretary could not rely on Maggie's microcephaly to rebut a prima facie case of causation because her microcephaly is, in the court's view, "idiopathic." Although the Act excludes "idiopathic" factors from the "factors unrelated to the administration of the vaccine" that may rebut a prima facie case, the Secretary did not rely on such a factor here.

Idiopathic means "of unknown cause." Accordingly, in order to rebut the presumption, the Secretary cannot rely exclusively on medical evidence showing that there is no known cause of the child's injury or on evidence showing that there is no established relationship between the vaccine and the child's injury. The Secretary must be able to point to an identifiable condition as an explanation for the claimant's injury. Here, the Secretary did point to a specific, preexisting condition—microcephaly—to explain Maggie's current condition. Because microcephaly is sufficiently well-defined, and because it logically eliminates the vaccine as the cause of Maggie's injuries, it is non-idiopathic within the meaning of the Vaccine Act.

The court of appeals held that the Secretary was relying on an "idiopathic" factor because the Secretary could not in turn identify the specific cause of Maggie's microcephaly. It is true that the cause of Maggie's preexisting condition is not fully understood. But that is almost always true in medicine. Congress could not have intended the term "idiopathic" to be applied at that level of generality, since to do so might effectively preclude the Secretary from ever rebutting a prima facie case. Thus, as the legislative history confirms, the court of

appeals took the requirement that an unrelated factor must be non-idiopathic one step further back than Congress intended.

The court of appeals' interpretation also would lead to consequences that Congress could not have intended. For example, under the court of appeals' interpretation, if the Secretary could prove that a child had only a partial brain at birth and that such a condition inevitably results in the kinds of injuries that the child suffers, a prima facie case could not be rebutted unless the Secretary could also establish what had caused the child to have a partial brain. Since Congress could not have intended to permit compensation in circumstances in which the evidence shows that a preexisting condition and not the vaccine caused the child's injuries, the court of appeals' interpretation of the term "idiopathic" should be rejected.

## ARGUMENT

### THE COURT OF APPEALS ERRED IN HOLDING THAT THE VACCINE ACT AUTHORIZES COMPENSATION WHEN THE CHILD'S INJURY FIRST MANIFESTED ITSELF PRIOR TO ADMINISTRATION OF THE VACCINE

The court of appeals has interpreted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) to require compensation in circumstances in which logic dictates that a child's condition was not caused by the vaccine. The court arrived at that result by misinterpreting two provisions of the Act. Specifically, the court improperly construed 42 U.S.C. 300aa-11(c)(1)(C)(i), which sets forth the elements that a claimant must prove to establish a presumption that the vaccine has caused his or her condition, and 42 U.S.C. 300aa-13(a)(1)(B) (1988 & Supp. IV 1992), which sets forth what the Secretary must show to rebut that statutory



presumption. Each of those errors independently requires reversal of the judgment below.

#### A. Proof That A Symptom Of A Condition Occurred Within The Table Period After Administration Of A Vaccine Does Not Create A Presumption That The Vaccine Caused The Condition When The Condition Had Already Manifested Itself Prior To Administration Of The Vaccine

The Vaccine Act provides that a rebuttable presumption of causation exists when a claimant shows by a preponderance of the evidence that a child

> sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a specified] vaccine * * *, and the first symptom or manifestation of the onset of or the significant aggravation of any such illness, disability, injury, or condition * * * occurred within the time period after vaccine administration set for in the Vaccine Injury Table.

42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1)(A) (1988 & Supp. IV 1992). That statutory language creates a presumption of causation in two kinds of cases: those in which the claimant shows that the child first began to suffer from an injury or condition after administration of the vaccine, and those in which the claimant shows that the child suffered from a Table injury or condition prior to administration of the vaccine, but that it markedly worsened thereafter.

In this case, the special master carefully examined each of those possibilities. The special master found that Maggie's head size indicated that she had already suffered an encephalopathy before she received her third DPT vaccination. Pet. App. 30a-34a. The special master

also found that the seizures that Maggie experienced after administration of her third DPT vaccine did not significantly aggravate that preexisting condition. *Id.* at 34a-43a. The special master therefore properly concluded that respondents could not rely on the presumption of causation established by Section 300aa-11(c)(1)(C)(i).

The court of appeals did not disturb the special master's findings that Maggie suffered from an encephalopathy before she received her third administration of the DPT vaccine and that her condition did not markedly deteriorate afterwards. The court nonetheless held that there was a presumption that the DPT vaccine caused Maggie's current condition. It reasoned that the statutory phrase "first symptom or manifestation of the onset" means that a claimant is entitled to a presumption of causation as long as *any* symptom or manifestation of an underlying injury or condition happened to occur within the Table period. Pet. App. 5a-7a. That holding is incorrect for several reasons.

1. First, the court's interpretation cannot be reconciled with the plain meaning of the statutory text. The term "first" means "before all others," and the term "onset" means "a beginning or start." *The Random House Dictionary of the English Language* 723, 1354 (2d ed. 1987); see also *Webster's Third New International Dictionary* 856, 1577 (1986) (defining "first" as "being number one in a countable series," and "onset" as "beginning, commencement, start"); 5 *The Oxford English Dictionary* 957 (2d ed. 1989) (defining "first" as "[p]rior to all others in occurrence"); 10 *The Oxford English Dictionary*, *supra*, at 821 (defining "onset" as "beginning, commencement, start"). When an injury or condition has manifested itself prior to administration of a vaccine, a manifestation that occurs after administration cannot be the "first." And when an injury or condition had its start prior to administration of a vaccine, any manifestation that occurs after administration cannot be a manifestation of the "onset." Simply put, the phrase "first symptom or manifestation of the onset" cannot mean a *further* symptom of a *preexisting* injury.



In interpreting the meaning of legislation, "courts must presume that a legislature says in a statute what it means and means in a statute what it says." *Connecticut Nat'l Bank* v. *Germain*, 112 S. Ct. 1146, 1149 (1992). Because the court of appeals' interpretation is at odds with the statutory text, it must be rejected.

2. The court of appeals' interpretation also violates the principle that "a statute should be interpreted so as not to render one part inoperative," *Department of Revenue of Oregon* v. *ACF Industries, Inc.*, 114 S. Ct. 843, 848 (1994), because it fails to give any meaning to the statutory text creating a presumption of causation when the first symptom or manifestation of a "significant aggravation" of an injury or condition occurs within the statutory period after the administration of a vaccine. 42 U.S.C. 300aa-11(c)(1)(C)(i). Under the Act, "significant aggravation" means "any change for the worse in a *preexisting condition* which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. 300aa-33(4) (emphasis added). If, as the court of appeals concluded, a presumption of causation arises whenever any symptom occurs within the statutory period, there would never be a need for a claimant to establish a significant aggravation of a preexisting condition. As one special master has recently explained, under the court of appeals' interpretation, significant aggravation "need no longer be referenced in the resolution of any Table cases."

*Cepeda* v. *Secretary of the Dep't of HHS*, No. 90-2664V (Fed. Cl. July 12, 1994), slip op. 2.

Congress could not have intended for the significant aggravation presumption to be superfluous. Rather, as the definition of "significant aggravation" makes clear, that presumption must have been designed to cover the cases in which a Table condition was "preexisting" and had manifested itself prior to administration of the vaccine. Implicit in Congress's decision to authorize significant aggravation as a separate ground for recovery is that there cannot be a presumption of causation or an award of compensation where, as here, a condition that manifested itself prior to administration of the vaccine did *not* get markedly worse afterwards.

The legislative history to the Vaccine Act confirms that natural reading of the statutory text. As explained in the House Report, the Act "does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g. a child with monthly seizures who, after vaccination, has seizures on a daily basis)." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 14-16 (1986). The court of appeals' decision fails to give effect to that congressional intent.

3. Had Congress intended to create a presumption like the one imposed by the court of appeals, it surely would have done so in far simpler terms. Instead of providing that a claimant must show that the first symptom or manifestation of the onset or significant aggravation of the condition occurred within the statutory period, Congress could simply have provided that the claimant must show that "a symptom or manifestation of the condition occurred within the time



period after vaccine administration set forth in the Vaccine Injury Table." The language Congress chose shows that it decided to create a presumption where the claimant could show not only that a symptom of the condition occurred in the statutory period, but also either that there was no symptom or manifestation of the condition prior to administration of the vaccine, or, if there was, that there was a marked deterioration in that preexisting condition after administration of the vaccine.

That choice by Congress is a logical one. When a claimant can show that the first symptom of onset or significant aggravation of a condition occurred within a short time after administration of a vaccine, there is at least a substantial likelihood that the vaccine might have caused that condition. Creating a presumption of causation in such circumstances is therefore consistent with the manner in which presumptions are recognized as a general matter. See *NLRB* v. *Baptist Hosp., Inc.*, 442 U.S. 773, 787 (1979) (presumption appropriate where there is "a sound factual connection between the proved and inferred facts"); *International Bhd. of Teamsters* v. *United States*, 431 U.S. 324, 359 n.45 (1977) (proof that employer has engaged in a policy of discrimination creates sufficient likelihood that employer has engaged in discrimination in an individual case to shift the burden of proof); *Price Waterhouse* v. *Hopkins*, 490 U.S. 228, 262-266 (1989) (O'Connor, J., concurring in the judgment) (proof that discrimination is a substantial factor in a decision creates sufficient likelihood that discrimination is the but-for cause to shift burden of proof). When a condition for which a claimant seeks recovery has already manifested itself prior to administration of the vaccine and the condition did not markedly worsen afterwards, however, there is no realistic possibility that the vaccine caused the condition. The creation of a

presumption of causation in those circumstances therefore would make no sense.

4. The court of appeals appeared to recognize that the phrase "first symptom or manifestation of the onset" in Section 300aa-11(c)(1)(C)(i) requires a showing that the first of all symptoms of the condition occurred after administration of the vaccine. Pet. App. 5a. The court concluded, however, that the language in Section 300aa-14(a) that serves as a heading for the statutory time periods for Table injuries dictates a different conclusion. Pet. App. 5a. That heading reads: "Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration." 42 U.S.C. 300aa-14(a) (Supp. IV 1992). According to the court of appeals, Section 300aa-14(a), unlike Section 300aa-11(c)(1)(C)(i), provides that "the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, that the first of all manifestations must so occur." Pet. App. 5a.

There is, however, no relevant distinction between Section 300aa-11(c)(1)(C)(i) and Section 300aa-14(a). Both provide that the symptom or manifestation in the Table period must be "the *first* symptom or manifestation of the *onset* or of the significant aggravation" of the condition (emphasis added), not simply "a" or "any" symptom or manifestation of the condition. If there were a difference between the two Sections, however, Section 300aa-11(c)(1)(C)(i) should take precedence over Section 300aa-14(a), not the other way around. The language in Section 300aa-14(a) cited by the court of appeals is simply a heading that summarizes the rule in shorthand form. In contrast, Section 300aa-11(c)(1)(C)(i) formally sets forth the elements that a claimant must establish to trigger the statutory presumption of causation. See 42 U.S.C. 300aa-13 (1988 & Supp. IV 1992).



The court of appeals also purported to find support for its interpretation in the manner in which residual seizure disorders are addressed in the "Qualification and aids to interpretation," which appears in subsection (b) of Section 300aa-14, following the Table. There, the Act provides that a residual seizure disorder may be found if the claimant "did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved." 42 U.S.C. 300aa-14(b)(2). The court of appeals reasoned that, because the Act places no such limitation with respect to encephalopathies, Congress must not have intended to require claimants to show that there was no preexisting symptom of that injury or condition. Pet. App. 5a-6a. The special provision on seizure disorders was necessary, however, because seizures accompanied by high fevers may not be symptomatic of a seizure disorder. To avoid any uncertainty about whether the existence of pre-vaccination seizures accompanied by high fevers would preclude a showing of post-vaccination onset, Congress made clear that they would not. Thus, the provision does not demonstrate that Congress intended to require claimants to show the absence of prior symptoms or manifestations in residual seizure disorder cases, but not in others. Instead, it clarifies how the general statutory requirement—that a claimant must show that a manifestation that occurred within the statutory period was the first such manifestation—should be applied in the special circumstances of alleged residual seizure disorders.

Finally, the court of appeals attributed significance to the provision in the Act that permits a prima facie case to be defeated upon proof by a preponderance of the evidence that the injury or condition was due to "factors

unrelated to the administration of the vaccine," 42 U.S.C. 300aa-13(a)(1)(B) (1988 & Supp. IV 1992), a term that may include "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances," 42 U.S.C. 300aa-13(a)(2)(B). According to the court, "[i]t would make no sense to allow proof by the Secretary of birth trauma as a factor unrelated if the petitioner were required to prove that no such preexisting injury occurred as an element of the Table case." Pet. App. 6a. That reasoning is flawed.

There may well be cases in which a child has a preexisting condition, but no signs of that condition appeared prior to administration of the vaccine. There may also be cases in which signs of the condition appeared, but they were unobserved or unrecorded. In such circumstances, the claimant may establish a prima facie case of causation by showing that the first symptom or manifestation of the condition occurred within the Table period. The "factors unrelated" provision serves the distinct purpose of permitting the Secretary to rebut that prima facie case by showing that, even though the record does not establish that there was a prior symptom or manifestation of the injury or condition, it nonetheless is due to an unrelated *factor*, such as birth trauma. See *Knudsen* v. *Secretary of Dep't of HHS*, No. 93-5107 (Fed. Cir. Sept. 9, 1994), slip op. 6-7. The "factors unrelated" provision is therefore entirely compatible with the requirement that the claimant must show that a symptom or manifestation that occurred within the Table period was the "first" such symptom or manifestation of the "onset" of the injury or condition.

5. In sum, in order to establish a presumption of causation, it is not enough for a claimant to show that a symptom or manifestation of a Table condition happened



to occur in the statutory period. The claimant must also establish either that there was no previous symptom or manifestation of that condition, or that the preexisting condition markedly worsened after administration of the vaccine.

### B. The Secretary May Rebut A Prima Facie Case Of Causation By Proving That An Identified Preexisting Condition Caused The Injury, Even Though The Specific Cause Of That Condition Is Itself Unknown

The court of appeals likewise erred in holding that the Secretary could not rely on Maggie's preexisting microcephaly to rebut a prima face case of causation. The Act expressly provides that compensation shall be awarded if the special master or court finds that the petitioner has demonstrated by a preponderance of the evidence the matters necessary to recover (including the predicate circumstances for invoking the rebuttable presumption created by the Table), and "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300-13(a)(1)(A) and (B) (1988 & Supp. IV 1992). The latter clause sets out the basis for the Secretary to rebut the presumption of causation.

The special master found that Maggie's microcephaly was unrelated to administration of the vaccine and that it marked her as a child likely to experience the very developmental problems that she ultimately encountered as she matured. Pet. App. 42a-43a. In particular, the special master found that "there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone." *Id.* at 38a. Those findings were sufficient to support the conclusion

that Maggie's current condition is due to "factors unrelated to the administration of the vaccine."

The court of appeals did not disturb the special master's findings, and it acknowledged that, "[l]ogically, these findings point to some preexisting condition, and not the vaccine, as the source of Maggie's injuries." Pet. App. 8a. The court nonetheless held that the Secretary had not established a "factors unrelated" defense because, in its view, Maggie's microcephaly was, in turn, "idiopathic." *Id.* at 8a-9a. That holding is in error. The Act provides that the term "factors unrelated to the administration of the vaccine" "does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition," 42 U.S.C. 300aa-13(a)(2)(A), and it thereby precludes the Secretary from relying on an "idiopathic" factor to rebut a prima facie case of causation. But the Secretary did not rely on such a factor here.

1. Medical dictionaries uniformly define "idiopathic" as "of unknown cause." *International Dictionary of Medicine and Biology* 1398 (1976); *Stedman's Medical Dictionary* 762 (25th ed. 1990); *Dorland's Illustrated Medical Dictionary* 815 (27th ed. 1988); *The American Medical Association Encyclopedia of Medicine* 566 (1989). The core of what Congress was attempting to preclude by ruling out reliance on "idiopathic" factors is apparent from that definition. The Secretary could not attempt to rebut a prima facie case by relying on a statement from an expert such as: "I have no idea what caused the injury, but it could not have been the vaccine."

That statutory protection for the claimant is important. There are medical studies that show that the overall frequency of certain identified conditions in children who receive the DPT vaccine is the same as it



is in children who do not receive the vaccine. See *Grant* v. *Secretary of Dep't of HHS*, 956 F.2d 1144, 1148-1149 (Fed. Cir. 1992). Outside the context of the Vaccine Act, such studies have been found to be sufficient by themselves to defeat a finding of causation. See, *e.g.*, *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823, 830 (D.C. Cir. 1988), cert. denied, 493 U.S. 882 (1989). Because the Vaccine Act excludes reliance on "idiopathic" or "unknown" factors from consideration as "factors unrelated to the administration of the vaccine," the Secretary could not rely on such studies alone to rebut a prima facie case. Similarly, the Secretary could not attempt to rebut a prima facie case by relying on a condition that has no medical meaning or significance other than to identify a situation in which the cause of the injury is unknown. For example, the Secretary could not attempt to rebut a prima facie case of a vaccine-related death by proving that a child died from sudden infant death syndrome (SIDS) because SIDS "is not an illness or injury, but an idiopathic diagnosis used to describe the otherwise unexplained death of an infant." *Hodges* v. *Secretary of Dep't of HHS*, 9 F.3d 958, 963 (Fed. Cir. 1993) (internal quotation marks omitted).

What these examples have in common is the absence of any identifiable condition as an explanation for the person's injuries. When the Secretary is unable to point to such an identifiable condition, the Act requires that the claimant receive the benefit of the doubt on the issue of causation, even though it is unclear whether the vaccine actually caused the injury. Here, however, the Secretary *did* identify a specific, preexisting condition—microcephaly—to explain Maggie's brain injury. Because that condition is sufficiently well-defined, and because it logically eliminated the vaccine as the cause

of Maggie's current injuries, it is non-idiopathic within the meaning of the Vaccine Act.

2. The court of appeals nonetheless concluded that the Secretary was relying on an "idiopathic" factor because the Secretary could not in turn identify the cause of Maggie's preexisting microcephaly. Pet. App. 7a-8a. It is true that the cause of Maggie's underlying condition is not fully understood and that it could therefore be termed "idiopathic" in that broader sense. In medicine, however, the cause of an event is almost never fully understood; there is almost always more to be learned. Congress could not have intended the term "idiopathic" to be applied at that level of generality, however, since to do so might effectively preclude the Secretary from ever rebutting a prima facie case.

The court of appeals lost sight of the fact that the term "idiopathic" is used in the Act for a specific purpose: to limit and define the term "factors unrelated to the administration of the vaccine," which defeats a showing of causation under the Act. The term should be construed with that purpose in mind, and thereby with reference to the degree of relatedness and possible causal nexus between the child's current injury or condition and the "factor" to which the injury or condition is (according to the Secretary's evidence) "due." When the term "idiopathic" is thus read in the context of the Act as a whole, *Brown* v. *Gardner*, No. 93-1128 (Dec. 12, 1994), slip op. 3, it is clear that the court of appeals took the requirement that an unrelated factor must be non-idiopathic one step further back than Congress intended. The Act gives the claimant the benefit of the doubt in cases in which the Secretary cannot point to any identifiable condition that justifies elimination of the vaccine as the cause of the injury or condition. It does not require compensation in circumstances in which the Secretary can point to a specific condition that *does* logically eliminate the vaccine as the cause of the child's current injury, simply because the cause of that specific condition is, in turn, unknown.



The legislative history supports that reading of the statutory text. The House Report states that "factors unrelated to the administration of the vaccine" cannot include "speculative or hypothetical matters or explanations." H.R. Rep. No. 908, *supra*, at 18. It makes clear, however, that the Secretary may prevail by relying on "other, defined illnesses or factors." *Ibid.*

3. The court of appeals' broader definition of "idiopathic" leads to consequences that Congress could not have intended. The Federal Circuit's previous decision in *Koston* v. *Secretary, Dep't of HHS*, 974 F.2d 157 (1992), is illustrative. There, the Secretary introduced evidence that the child's condition was caused by Rett Syndrome, a condition manifested by mental regression and peculiar behavioral symptoms. *Id.* at 160-161. Even though the Secretary could establish that this condition is always present from birth and therefore logically eliminated the vaccine as the cause of the child's condition, the court held that it was idiopathic (and therefore could not be regarded as a "factor unrelated to the administration of the vaccine") because medical science had not yet established the specific cause of Rett Syndrome. *Ibid.*

Similarly, under the court of appeals' interpretation, even if the Secretary could prove that a child had only a partial brain at birth and that such a condition invariably results in the kind of injury or disability from which the child suffers, a prima facie case could not be rebutted unless the Secretary were able to identify what had caused the child to have a partial brain. It is implausible that Congress would have intended that result.

In seeking to justify its holding in *Koston*, the court of appeals stated that it was its duty to construe the Act as written, even if that construction would (as the Secretary argued) produce absurd consequences. 974 F.2d at 161. Even if the text of the Act seemed unambiguous on the point, a court's duty is not so unyielding. See, *e.g.*, *Public Citizen* v. *United States Dep't of Justice*, 491 U.S. 440, 453-454 (1989); *Church of the Holy Trinity* v. *United States*, 143 U.S. 457, 459 (1892). In fact, however, the term "idiopathic" is susceptible of a far narrower construction than the one adopted by the court of appeals. In such circumstances, the court had a duty to avoid an interpretation of the statutory language that would produce absurd results. *Haggar Co.* v. *Helvering*, 308 U.S. 389, 394 (1940); see also *Public Citizen*, 491 U.S. at 454-455. Because Congress could not have intended to permit compensation in circumstances in which the evidence shows that a preexisting condition, and not the vaccine, caused the child's injury or disability, the court of appeals' construction of the term "idiopathic" should be rejected.



## CONCLUSION

The judgment of the court of appeals should be reversed, and the case should be remanded to the court of appeals for review of the judgment of the Court of Federal Claims under the proper legal standards.

Respectfully submitted.

DREW S. DAYS, III
*Solicitor General*

FRANK W. HUNGER
*Assistant Attorney General*

EDWIN S. KNEEDLER
*Deputy Solicitor General*

IRVING L. GORNSTEIN
*Assistant to the Solicitor General*

BARBARA C. BIDDLE
RICHARD A. OLDERMAN
KAREN P. HEWITT
*Attorneys*

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No. 94-372



In The

# Supreme Court of the United States

October Term, 1994

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,

*Petitioner,*

v.

MARGARET WHITECOTTON, et al.,

*Respondents.*

**On Writ Of Certiorari**
**To The United States Court Of Appeals**
**For The Federal Circuit**

## BRIEF FOR THE RESPONDENTS

ROBERT T. MOXLEY*
RICHARD GAGE
GAGE & MOXLEY
623 W. 20th Street
Post Office Box 1223
Cheyenne, Wyoming 82003
(307) 632-1112

PROF. PETER H. MEYERS
Vaccine Injury Project,
National Law Center
George Washington University
2000 G Street, Suite 200
Washington, D.C. 20052
(202) 994-7463

JOHN S. CAPPER IV, Esq.
BERRY, CAPPER & TULLEY
P.O. Box 429
Crawfordsville, Indiana 47933
(317) 362-7340

*Counsel for the Respondents*
*Counsel of Record



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## COUNTERSTATEMENT OF THE QUESTIONS PRESENTED

1. When a petitioner (child) who has a preexisting condition seeks compensation for a vaccine-related injury under the National Childhood Vaccine Injury Compensation Act, and establishes a "Vaccine Table" injury, does the Act create a presumption of compensability and place the burden of proof on the Secretary to rebut this presumption with proof by a preponderance of the evidence that "factors unrelated" to the vaccine caused the child's adverse Table-time reaction?

2. If so, can the Secretary meet her burden by relying on either a) an "idiopathic" pre-existing condition (a condition without a known cause) or b) speculation that such pre-existing condition may have caused the petitioner to have suffered the "Vaccine Table injury?"

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No. 94-372

In The

# Supreme Court of the United States

October Term, 1994

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,

*Petitioner,*

v.

MARGARET WHITECOTTON, et al.,

*Respondents.*

**On Writ Of Certiorari**
**To The United States Court Of Appeals**
**For The Federal Circuit**

## BRIEF FOR THE RESPONDENTS

## STATEMENT OF THE CASE

### A. The Vaccine Injury Compensation Proceedings on Behalf of Margaret "Maggie" Whitecotton

#### 1. Maggie Whitecotton's Clinical History

Margaret ("Maggie") Whitecotton was born on April 22, 1975. Her hospital records indicated that she was a small but healthy child at birth. Her length and head circumference were in the second to third percentile, and her birth weight was 6 lbs. 7oz., in the 20th percentile. Her growth (weight, head circumference, and length) was monitored in regular pediatric visits, and found to be normal up to age four months. In fact, as the Federal Circuit stated below, "Maggie was healthy, developmentally and physically, until she

received her third diphtherja-pertussis-tetanus (DPT) vaccination on August 18, 1975." Pet. App. 2a.[1]

A great deal of emphasis was placed on Maggie's head circumference in the court decisions below. The circumference of Maggie's head at birth was 12.5 inches or 31.75 cm. *Id.* at 33a. This head circumference placed her in approximately the 2.5 percentile for her age and sex, *Id.* at 32a. In other words, approximately 25 out of every 1000 girls are born with Maggie's head circumference. Statistically, this placed Maggie at the borderline of two standard deviations below the average or "mean" head circumference for a child of the same sex and age. *Id.* at 32a-33a. A baby with a head circumference three standard deviations from the mean would be at or below the 0.35 percentile.

Maggie's condition at birth could be described as "borderline microcephalic". The term "microcephalic" means "small head," and it can range from a borderline condition very close to the average head size to a very extreme condition characterized by a head circumference even 4 or 5 standard deviations from the mean.[2]

---

[1] The following abbreviations are used in this brief:
Pet. App. – Appendix to Petition for Writ of certiorari
Pet. Br. – Secretary's Principal Brief in this Court
JA – Joint Appendix filed in this Court
Tr. – Transcript of proceedings at the hearing below
Exh. – Exhibits introduced at the hearing below

[2] For clinical purposes, microcephaly has been defined by some medical authorities as a head circumference smaller than two standard deviations from the mean, while many other medical authorities – probably the majority – define it as a head circumference smaller than three standard deviations from the mean. Depending on which definition is adopted, Maggie was or was not "borderline microcephalic" at birth. The government's sole medical expert below, Dr. Owen B. Evans, acknowledged that while he considered Maggie to be "microcephalic", Maggie would not be considered "microcephalic" by some accepted definitions of that term, Tr. 247-48, JA at 58. The special master who presided over the hearings characterized Maggie's condition as "at least borderline microcephalic at birth. . . ." Pet. App. 32a-33a. *See also* Kemp, Current Pediatric Diagnosis and Treatment, Ninth ed., chapter 23, page 692 (defining microcephaly as "a head circumference three SD or more below mean for age and sex"); Rudolph, editor, Pediatrics, 17th ed., page 402 ("Most investigators have defined microcephaly as a occipital-frontal circumference (OFC) of less than three standard deviations (SD) below the mean for age and sex."); Pediatric Neurology, 3rd ed., Harper and Row, page 71 ("For standardization, microcephaly is arbitrarily defined by a cranial circumference less than three standard deviations below the normal for age and sex."); Wasserman, Survey of Clinical Pediatrics, 7th ed., page 346 ("Microcephaly . . . the head circumference is always three standard deviations below the mean") Signs and Symptoms in Pediatrics, Lippencott, Chapter 22, page 112 ("There is some disagreement about the clinical definition of microcephaly. The criterion of head circumference more than two standard deviations . . . has been used; measurements three or more standard deviations below the mean have also been recommended.")



Despite her small size, Maggie's medical records showed that she was developing normally, with no sign of any problems, until she began having seizures immediately after she received her third DPT and second oral polio vaccine on August 18, 1975, when she was almost four months old. J.A. at 11.

Maggie began having clonic seizures in her mother's presence about six hours after receiving the vaccines. Pet. App. 27a; Tr. 18-19. Maggie suffered three or four seizures every 20-30 minutes which were characterized by flinching and jerking of Maggie's upper extremities and blinking of her eyes. Tr. 18-19.

Maggie's mother took her to an emergency room that evening, where she was examined by a physician. Pet. App. at 30a. The next morning, Maggie's mother observed the same jerking motions, and she was referred to the chief of pediatric neurology at Riley Hospital. Maggie was admitted and underwent extensive evaluation. The conclusion was that she had suffered a vaccine encephalopathy manifested by her seizures, but appeared otherwise normal from a neurological perspective. The physicians stated that Maggie's seizures "were most likely secondary to the pertussis vaccine which she had received earlier in the day." *Ibid.*

Maggie's development began to slow significantly at this point, including the growth of her head, which slowed so much "that it fell off the growth curve." J.A. 11. Maggie began to lose weight, engaged in projectile vomiting (a possible indication of inflammation of the brain), and she regressed in her ability to raise her feet and hold her head erect. Tr. 26, 30.

Maggie continued to experience a series of seizures over the next several years[3]. In recent years, she "needs constant twenty-four hour monitoring for seizures so that if one develops she can receive the appropriate help." J.A. 14.

Today, Maggie is "disabled both mentally and physically." Pet. App. 37a. She is felt to function at the level of a two to four year old child. Her problems are "compounded by the fact that she is non-verbal and therefore cannot ask questions, talk to other staff or clients, or make her ideas, wants or needs known." J.A. 13. She has cerebral palsy, hip and joint problems, and is not able to walk. Pet. App. 37a. Her condition is stable, and no significant change in her condition is anticipated. She is "for all practical purposes, totally dependent on others for her needs." *Ibid.*

## B. The Statutory Scheme

The central feature of the Vaccine Act involved in this case is the Initial Vaccine Injury Table, 42 U.S.C. § 300aa-14 (a). This Table lists certain injuries and conditions, which, if found to occur within a prescribed period of time following vaccination, create a rebuttable presumption of entitlement to compensation. There are two categories of "Table-time" injury, (1) table-time "onset" cases and (2) table-time "significant aggravation" cases. In such cases, the petitioners do not need to adduce proof of actual causation, because causation is presumed. Once the petitioner establishes a prima facie case of Table Injury, and the presumption of compensability arises, the burden then shifts to the government, which must prove

[3] On February 24, 1976, Maggie experienced a major seizure, and was reported unarousable at the hospital. Exh. H-3. On January 16, 1977, Maggie experienced another major seizure, and the hospital admission records voted that she had febrile convulsions. Exh. H-8. On August 28, 1979, Maggie had another seizure. Exh. H-12. Maggie received a DT "booster" shot on March 21, 1980, and the next day she experienced a grand mal seizure. Pet. App. 29a. Maggie's mother testified to additional focal seizures over the next few years. *Ibid.* The last mention of possible seizure activity was noted by the Intensive Care Unit staff at Riley Hospital in 1990 while Maggie was on a ventilator recuperating from major surgery for correction of spasticity-induced kyphosis.



by a preponderance of the evidence that the claimed injury is attributable to "factors unrelated" to the "administration of" the vaccine. 42 U.S.C. § 300aa-13 (a) (1) (B). The Act goes on to indicate that the term "factors unrelated" does not include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. § 300aa-13 (a) (2) (A).

If a petitioner seeks compensation for an injury which is not listed in the Vaccine Injury Table, or for an injury which occurred after the expiration of the prescribed time period following vaccination, the petitioner is not precluded from obtaining compensation. However, for these non-Table Injury cases Congress placed the burden on the petitioner to prove causation in fact. 42 U.S.C. § 300aa-11 (c) (1) (C) (ii). These burdens of proof and presumptions as to causation are a central feature of the Act[4].

The petitioner's Brief sets forth most of the pertinent statutory provisions. However, three significant provisions, (1) the definition of DPT-induced "residual seizure disorder," (2) provisions which link seizures to "encephalopathy," and 3) provisions relating to a child's ultimate outcome, were omitted. Thus, Respondents reproduce the operative language of these sections:

The definition of "residual seizure disorder" is found at 42 U.S.C. § 300aa-14 (b) (2) (B):

> "(b) QUALIFICATIONS AND AIDS TO INTERPRETATION. – The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table . . .

[4] Additional requirements to qualify for compensation under the Act, for both Table and non-Table cases, include: The petitioner's injury must have lasted more than six months, the petitioner must have incurred more than $1,000 in unreimbursed medical expenses, the vaccine must have been administered in the United States, and the petitioner must not have previously collected a damage award in a civil action for the injury. 42 U.S.C. §§ 300aa-11 (c) (1) (D) (i), 300aa-11 (c) (1) (A), (B), and (E).

> "(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion- . . . before the first seizure or convulsion after the administration of the vaccine involved and if . . .
>
> > "(B) . . . the first seizure occurred within three days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after . . . "

The secretary has provided the language of 42 U.S.C. § 300aa-14 (b) (3) (A), the statutory definition of encephalopathy, but omits the pertinent language of § 300aa-14 (b) (4) which states:

> (4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs . . . "

Finally, Respondents rely on the table language in 42 U.S.C § 300aa-14(a) and (a) i.e.:

> "(a) . . . The following is a table of vaccines, the injuries, disabilities, illnesses, conditions and deaths, and the time period in which the first symption or manifestation . . . is to occur . . . for purposes of receiving compensation . . . :
>
> I DPT . . .

| Illness, disability injury or condition covered: | Time period for first symptom . . . |
|---|---|
| * * * | |
| D. Residual Seizure disorder ..... | 3 days |
| E. Any acute complication or sequela (including death) of an illness, disability, injury or condition referred to above which . . . arose within the time period prescribed ..... | Not Applicable |



The Vaccine Act creates a unique federal no-fault compensation program for individuals alleging injury or death due to the administration of one of the mandatory childhood vaccines.[5] Petitions for compensation are adjudicated in the United States Court of Federal Claims. The petition is defended by the Secretary of Health and Human Services, who is in turn represented by the Department of Justice.

The Act took effect on October 1, 1988. Persons alleging injury due to vaccines administered prior to that date have the option of seeking compensation under the Act, or filing a traditional tort suit. Persons alleging injury due to vaccines administered on or after that date are prohibited from filing a civil action seeking more than $1,000 in damages unless the person has first filed a claim under the Act and exhausted its procedures, including rejecting any award of compensation under the Act. *See* 42 U.S.C. §§ 300aa-16, and 300aa-21 (a).

### 1. The Legislative History of the Act

The Act was prompted by a unique marriage of parents' organizations, vaccine manufacturers, and the public health community. Vaccine manufacturers, citing the costs and uncertainties of defending vaccine claims in civil court, threatened to discontinue vaccine production. Many pharmaceutical companies had already pulled their products at the time that Congress was debating the Act (including two of the three companies marketing the DPT vaccine), and there was great concern that the supply of vaccines in the United States would dry up. *See generally*, Denis J. Hauptly and Mary Mason, "The National Childhood Vaccine Injury Act," Fed. Bar N. & J., Vol. 37, no. 8, pg. 452, 452-53 (1990) [hereafter "Hauptly"].

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[5] All fifty states and the District of Columbia have enacted laws which generally require proof of immunization before a child enters school. Subcommittee on Health and the Environment of the House Commission on Energy and Commerce, 99th Congress, 2d Sess., Childhood Immunizations 103-05 (Comm. Print 1986). In most states, immunization is required against seven diseases: Polio, measles, mumps, rubella, diphtheria, tetanus, and pertussis. *Id.* at 1.

Parents groups, such as Dissatisfied Parents Together (DPT), were concerned about the extensive delay, substantial costs, and uncertain results of traditional tort actions seeking compensation for vaccine-related injuries. These groups argued that any compensation program must necessarily insure a just and expedited mechanism to protect children who may be injured by adverse reactions to vaccines. *Ibid.*

The public health community was concerned, on the one hand, with the possible withdrawal of vaccine manufacturers, and the consequences that would follow from a lack of supply of vaccines in the United States. These health officials were also concerned, on the other hand, that public confidence in immunization program was being eroded by numerous reported severe reactions (especially to the pertussis vaccine), and the difficulty in obtaining compensation for injured children. These developments, which threatened to substantially reduce immunizations in the United States, were a cause of great concern to the public health community, and were an important motivation behind the vaccine Act. *Ibid.*; *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2-3 (1st Cir. 1994)[6].

### 2. The Legislative Definition of "Encephalopathy."

The Congressional definitions of injury are couched in medical terminology, but are not always consistent with the way that such terms are used by medical doctors[7]. Of special

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[6] Currently, 98% or more of American children are fully immunized by the time of school entry. David S. Fedson, "Adult Immunization: Summary of the National Vaccine Advisory Committee Report," JAMA, Vol. 272, No. 14, pg. 1133 (Oct. 12, 1994).

[7] This point is underscored by the discussion in the respondent's report, JA p. 21, at 24. The Respondent's expert acknowledges the "legal question," but then gives a "medical" explanation:

> "As for the legal question of whether this child had a post-immunization encephalopathy, there is no clinical evidence to support an encephalopathy following the immunization such as altered consciousness, focal or diffuse neurologic signs, or other impairment of brain function ***aside from the brief seizures which were observed***. The abnormal disorganization and ***slowing of the EEG could possibly support a diagnosis of encephalopathy***; however, in the clinical picture of co-existing seizures this is not diagnostic." (Emphasis added.)



concern to this case are the **overlapping** definitions of "encephalopathy" and "residual seizure disorder." Encephalopathy **is shown** by seizures, as a matter of law:

> "The term 'encephalopathy' means ***any*** significant ***acquired abnormality*** of, or injury to, or impairment of function ***of the brain***. Among the ***frequent manifestations*** of encephalopathy ***are focal and diffuse neurologic signs***, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, ***with*** or without ***convulsions . . . Encephalopathy*** usually ***can be documented by*** slow wave activity on an ***electroencephalogram***." (Emphasis added.) 42 U.S.C. § 300aa-14 (b) (3) (A)

Even though a "residual seizure disorder" is also a separately defined injury, under 42 U.S.C. § 300aa-14 (b) (2) (B), the key to the finding of a Table injury herein – assuming *arguendo* that the record doesn't have **ample** proof of the residual seizure disorder – is the fact that the case qualifies as an "encephalopathy" under the Table **via the seizures**. They occurred in the statutory "time period in which the first symptom or manifestation of onset . . . is to occur after vaccine administration for purposes of receiving compensation under the program." 42 U.S.C. § 300aa-14 (a).

It is the obvious import of § 300aa-14 (b) (3) (A), quoted *supra*, read together with section 14 (b) (4), that "encephalopathy" embraces seizures, and is conclusively shown by seizure activity.

### 3. The Statutory Limitations upon "Factors Unrelated to the Administration of Vaccines."

The Secretary in her brief sets forth the passages of the Act which concern "factors unrelated," respectively, 42 U.S.C. § 300aa-13 (a) (2) (A) and (B) (Pet. Br. pp. 3-4) and 42 U.S.C. § 300aa-14 (b) (3) (B) (*Id.* pp. 5-6). But neither the

Secretary nor her *amicus* acknowledge the clear narrowing of the statutory focus where a Table case is concerned. Under the "general rule" of § 13, "factors unrelated" **includes but is not limited to** the listed four categories of "infections, toxins, trauma, or metabolic disturbances." But under the Table, the four listed factors are **exclusive**[8].

Thus, the provisions of § 300aa-13 (1) require the Vaccine Court to make findings as to the petitioner's showing of the elements of the petition, and the absence of factors unrelated. The open-ended recitation in § 300aa-13 (2) (B) that only "includes" the four factors is "(f)or purposes of paragraph (1)." However, when the statute gets to a Table case, it narrows the focus. At 42 U.S.C. § 300aa-14 (b) (3) (B) the Act states,

> "If . . . an encephalopathy ***was caused by*** infections, toxins, trauma ***or*** metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table . . . " (emphasis added).

Speaking of this quoted passage which is from the aids and qualifications to interpretation, the Act at 42 U.S.C. § 300aa-14 (b) states that such provisions "shall apply to the Vaccine Injury Table . . . "

## C. The Course of the Case Below.

Petitioners applied for vaccine compensation via a complaint filed on August 2, 1990. On December 21, 1990, the

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[8] This must account for the apparent confusion in the mind of the *amicus* as it discusses the case of *Knudson v. Secretary of DHHS*, 35 F.3d 543 (Fed. Cir. 1994). *Knudson* is cited as "**allowing**" proof – which the government **could not do** in that specific case – by an "unknown" virus. The cause-and-effect standard of proof properly applied by the Court of Appeals in that case defeated the defense. But the *amicus* fails to acknowledge that the **proof** of cause by unknown virus is **still proof**, of **known causation. Knudson** properly requires that the **mechanism** of causation be shown. Moreover, the *amicus* fails to see the distinction that the statute **allows** proof of alternate causation by "infection" under the Table, via § 300aa-14 (b) (3) (B), but **not** by "idiopathic" factors. *See*, Argument Three, section E, *infra*.



Secretary of Department of Health and Human Services filed a "respondent's report," recommending that the special master deny compensation. The Secretary relied upon the opinion of a Dr. Owen B. Evans, asserting that Maggie Whitecotton suffers a preexisting "organic brain syndrome." (Respondent's Report, page 5, JA at 23). The report acknowledged seizure activity in Table Time, but asserted a failure to demonstrate an encephalopathy. *Id.*, page 6 (JA at 24). The report also asserted that there were not enough seizures to qualify Maggie's condition under the concept of "residual seizure disorder." *Id.*, at 6-7 (JA at 24).

There ensued the routine course of status conferences which precede a decision, and trial if necessary, in these matters. The special master on the occasion of a January, 1991, status conference indicated an inclination to rule for petitioners. Subsequently, petitioners were instructed to begin the life care plan.[9] (See affidavit of counsel in support of amended Rule 60(b) motion, August 25, 1992, see also the Order of September 15, 1992, at page 5, JA at 80). Ultimately, on June 4, 1991, a trial was held in Indianapolis, Indiana.

### 1. The Initial Decision.

Witnesses for the petitioners were Maggie's mother, Kay Whitecotton; her treating physician, Ellen L. Kitts, M.D.; and Gerald E. Slater, M.D., a pediatric neurologist. Owen Evans, Jr., M.D., was the only defense witness.

The special master's decision issued on the 16th day of August, 1991. The special master's legal analysis was that the alleged "chronic organic brain syndrome . . . which preexisted the administration of the DPT," would be a "factor unrelated" to the vaccine. (Decision, slip opinion at 1, Pet. App. at 25a).

The special master found that Maggie's clinical course of seizures after the third DPT vaccine, on August 18, 1976,

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[9] The life care plan is ordinarily not initiated before a positive decision on entitlement. The cost of such planning, in the thousands of dollars, is a major administrative concern in the Program. *See, e.g., Knox v. Secretary of DHHS*, Case No. 90-330V (Cl. Ct. Spec. Mstr. Febr. 22, 1991).

**would** fit within the statutory criteria for a "residual seizure disorder" under section 14 of the Act. (Decision, slip opinion at 2-3, Pet. App. at 27a[10].) However, it was held that this specific condition did not last six months, and is not permanent, thus leading to the conclusion that as of 1991, "she does not presently have a compensable residual seizure disorder." (Decision, page 4, Pet. App. at 30a.) The decision went extensively into analysis of the **cause** of the current overall condition, concluding that it is the result of the preexisting condition, labelled as a "chronic organic brain syndrome." The special master saw Maggie's alleged "microcephaly" as a sign that she "suffered an encephalopathy sometime prior to the administration of the DPT." (Decision, page 7, 33a.)

Having discounted the Table Time seizures as the manifestation of "original injury" at the time of the DPT, the special master embarked upon the application of the "*Misasi* doctrine" which is applied[11] to the question of "significant aggravation" under the Act. Two factors were explored as manifestations of earlier injury, (1) rolling over at a "too early" age, and (2) swallowing problems, denied by the mother but supposedly shown by a treating physician's note (Exh. H-2, p. 3). Implying that Kay Whitecotton was **not** credible, the special master said of the physician's note: "the court considers it credible." (Decision, page 9, Pet. App. at 37a.) The court also stated unequivocally that, "(p)rior to the

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[10] The special master stated in a footnote, (fn. 4, Pet. App. at 27a), "This conclusion is based on a literal reading of § 14 (b) (2) (B) . . . " The special master went on to speculate that Congress may not have meant what the statute says.

[11] *Misasi v. Secretary of DHHS*, 23 Cl. Ct. 322 (1991), had been affirmed by the Claims Court on June 7, 1991. Its viability and legal correctness has not been settled. It was questioned in *Costa v. Secretary of DHHS*, Case No. 90-1476V (Cl. Ct. Spec. Mstr. Febr. 22, 1992) *remanded* 26 Cl. Ct. 866 (1992), and even partially repudiated by Special Master Baird in a manner approved by the Claims Court in the case of *Schumacher v. Secretary of DHHS*, 26 Cl. Ct. 1033, 1042 (1992). *See also O'Connor v. Secretary of DHHS*, 24 Cl. Ct. 428 (1991), approved by *Schumacher*, which involves a burden-shifting analysis not employed herein.



August 18 shot, Maggie was microcephalic.[12]" However, the Court went on that "beyond that, there were only some hints" of the alleged neurological condition. But, in "predicting the outcome" of the alleged preexisting condition, the special master stated as follows:

> "The fact that there was little evidence of complications of microcephaly prior to August 18, 1975, does not mean that Maggie would have developed normally . . . ***Based on her microcephaly alone, the court is able to predict with a high degree of certainty that Maggie would have been mentally retarded*** even if the DPT vaccine had not been administered to her on August 18, 1975 . . . there was a greater than 90% likelihood that Maggie would have been mentally retarded based on her microcephaly alone." (Decision, slip opinion at 10, Pet. App. at 37a-38a, emphasis added.)

The special master accepted the testimony of Dr. Evans, the government's expert, over that of Dr. Kitts, a treating physician. The special master noted agreement between both doctors that all of Maggie's problems stem from a single injury.

Significantly, Dr. Evans revealed on several occasions during his testimony that he does not believe that DPT can cause the type of permanent injury which Maggie has. In fact, Dr. Evans does not believe in **any** kind of DPT-induced permanent neurological injury. (TR at 237-38, 240-41, 286-87, JA at 54, 55, and 61.) Dr. Evans attributed the contemporary diagnosis of post-DPT encephalopathy to the possibility that the medical community **did** believe in the

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[12] The most significant question under the state of the record is how and whether the alleged headsize puts Maggie into the category of microcephaly. The decision goes scientifically and medically awry, in both factual and legal causation terms, for its failure to distinguish Maggie's borderline microcephaly (at the time of the injury) from the more severe microcephaly from which the special master extrapolated his prognosis in applying the *Misasi* test. The Court should not have to address this mixed issue of law and fact.

existence of permanent DPT injury, at the time of the examinations and work-ups. (TR at 286, JA at 61.)

### 2. Proceedings on Motion for Review.

Judge Turner of the Claims Court (renamed now to the Court of Federal Claims) affirmed Special Master Baird's decision, by virtue of an opinion dated January 14, 1992. It held that a condition which fits the "Table" definition of "residual seizure disorder" does not **compel** the finding of such a disorder, but that it is discretionary. The court also upheld the special master in "finding that Maggie did not suffer *the sequela* of a residual seizure disorder." (Opinion and Order, slip opinion at 7, Pet. App. at 18a emphasis added.) The Judge of the Claims Court found the decision not to be arbitrary[13].

### 3. The Second Decision.

The final proceedings in the Claims Court were commenced via the filing of a motion for relief from judgment and for rehearing. This March 30, 1992 motion was amended, and filed with additional exhibits on August 25, 1992.

The additional evidence addressed three points. First, the treating physicians refuted the finding of the "swallowing problem" which was the sole "symptomatic" manifestation of Maggie's alleged preexisting encephalopathy. Second, two treating physicians refuted the idea that Maggie's microcephaly preexisted the shot. Dr. Paul F. Bustion recounted his specific recollection (JA at 71) that Dr. Drew, the diagnosing physician in Indianapolis, had attributed her condition to the DPT. Dr. Foltz, who delivered Maggie, concurred in blaming

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[13] On all the appeals, the Whitecottons have asserted that the special master was arbitrary. In the RUSCFC Rule 60(b) order, he specifically asserted that the "swallowing problems," one basis of Dr. Evans's opinion, were insignificant to his own findings. (Order, JA at 83-84.) That is, Special Master Baird decided the case "based on the microcephaly alone." Moreover, Dr. Evans' other linchpins were Maggie's seizures, cerebral palsy, and mental retardation, **all of which manifested after the shot.** Transcript at 206, JA at 46.



the DPT, and stated that Maggie was not born microcephalic (JA at 75). Finally, the third point involved a showing by G. Paul DeRosa, M.D., that Maggie's hip problems were not congenital, but secondary to her cerebral palsy (JA at 76).

With the amended motion, petitioners also presented medical literature, from two treatises (Exh. HH and Exh. II). These were to amplify on the theory that the cerebral spinal fluid tests, showing demyelination, were corroborative of an actual adverse vaccine reaction at the time of Maggie's August 18, 1975 vaccination.

The matter was referred to the special master, and on September 15, 1992, the special master entered an order finding that all evidence but the letter from Dr. Bustion could have been discovered pretrial, and thus was not newly-discovered. None of the evidence, according to Special Master Baird, would change the result.

The Claims Court upheld the denial of the motion, and the appeal to the Federal Circuit, which had been stayed, resumed, with a separate appeal of the denial of the Rule 60(b) motion.

## D. The Competing Propositions Involved in the Litigation

### 1. The Government's Hypothetical Defense – "Organic Brain Syndrome."

To initially put the case in issue, the Secretary of Department of Health and Human Services filed a "respondent's report," dated December 21, 1990, recommending that the Office of Special Masters deny compensation for Maggie Whitecotton. The Secretary relied upon the opinion of Dr. Owen B. Evans, asserting that Maggie Whitecotton suffers a preexisting "organic brain syndrome." (See Dr. Evans' Report, JA at 21). The report acknowledged seizure activity in Table Time, but asserted a failure to demonstrate an encephalopathy[14]. (*Id.*, JA at 24)

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[14] Dr. Evans was cross-examined about his bias, shown *inter alia* by his statement (JA at 24) that no studies show a relationship between immunizations and

At trial, the Secretary's counsel proceeded from the assumption that "microcephaly" is a ***disease***, posing questions about disabilities whose "etiology" is "microcephaly." (Transcript at 88-89, Transcript at 207, JA at 46.)

According to her treating physician, Dr. Ellen Kitts, Maggie Whitecotton was **not** born with Cerebral Palsy, which is the expression of her vaccine related encephalopathy. There is **no evidence** of any defined causation process, other than an adverse reaction to vaccination, which produced the actual disability. The Respondents have asserted throughout that the special master in this case equated a questionable, borderline microcephaly with a major, full-blown disorder, ignoring a marked discontinuity of development **and** head growth, post-vaccination[15].

### 2. The Special Master's Medical Synthesis.

The special master saw Maggie's alleged "microcephaly" as a sign[16] that she "suffered an encephalopathy sometime prior to the administration of the DPT." (Decision, page 7,

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chronic or progressive neurologic disease. The special master came to his defense (TR 286-87), asking if his bias would prevent him from stating that there was or was not an encephalopathy in Table time. The doctor stated that it would not. However, Dr. Evans claimed there was no encephalopathy, despite the Table-time seizures, and abnormal EEG. (JA at 24.)

[15] As suggested by the secretary, the special master's significant aggravation analysis stated that "there was no dramatic turn for the worse in her condition indicating a permanent aggravation." Decision, Pet. App. at 42a. This is in the eye of the beholder, although the sufficiency of her case is a matter of law. Her present condition, compared to her condition before the shot, is obviously one of "markedly greater disability, pain or illness, accompanied by substantial deterioration of health." *See* 42 U.S.C. § 300aa-33 (4). And she was contemporaneously diagnosed with vaccine encephalopathy, certainly dramatic to her parents and treating physicians.

[16] In actuality, the special master used Maggie's **post-DPT** fall-off from the head size curve to corroborate his finding of pre-shot injury. The special master first discussed the head size up to the time of the shot, but stated, "(i)n the succeeding months, Maggie's head growth fell further behind the norm . . . "



Pet. App. at 33a.) The Court of Appeals acknowledged[17] **the special master's findings** as logically pointing to some other cause for her difficulties. Opinion, Pet. App. at 8a. But the special master could not say whether DPT caused or aggravated Maggie's cerebral palsy.

On the appeal below, the "Statement of Issues" in the Whitecotton's brief featured *inter alia* the following question:

> "3. MAY A SPECIAL MASTER FORMULATE HIS OWN OPINIONS ON MATTERS OF ULTIMATE MEDICAL FACT?"

The Whitecottons made various criticisms of the special master's reasoning. They asserted that "Special Master Baird's finding that the mental retardation was 'inevitable' is purely a matter of statistical analysis of head size as the proof of the defense." There was no such statistical analysis from an expert in the record. The Whitecottons also asserted that Special Master Baird called the evidence of swallowing problems "insignificant." (See Order, September 15, 1992, page 4, JA at 85.) In stark contrast, Dr. Evans stated that the head size and swallowing problems were the **only** signs of the chronic organic brain syndrome.

The Whitecottons asserted that it is improper for the special master to have found support from Dr. Slater, petitioners' expert, for the proposition that Maggie was microcephalic prior to the shot. The argument was made that it is not fair for the special master to give the facts significance which the expert does not[18].

### 3. Respondent's Position on Microcephaly in the Claims Court and the Court of Appeals.

The Whitecottons also took Special Master Baird to task for ignoring expert testimony **and** the import of medical

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[17] It was obviously irrelevant to the Court of Appeals that the factfinding was suspect, since the obviously idiopathic "factor unrelated" was **legally** irrelevant.

[18] The special master derived insights from the testimony of the treating physician, Dr. Kitts, with which she would most obviously disagree. And Dr. Slater clearly placed the most reliable indicators of microcephaly at a point several months later, far enough post-DPT for the shot to have been the cause.

literature filed by the petitioners (Exhibit S[19]). They made an unrebutted showing that children who fit the loose, most inclusive definition of microcephaly – adopted by the Court[20] – can indeed **as likely as not** be completely normal.

The Whitecottons pointed out a clinching factor in the analysis employed by the special master. This is the indisputable fact that there are **thousands** more children who fit the borderline definition of microcephaly (-2 SD below the mean), than who fit the more standard definition (-3 SD or more from the mean). It was pointed out that if the mild microcephaly exhibited by Maggie Whitecotton prior to her shot were **indeed** accompanied by a 90% chance of mental retardation, then such small-headed people would make up the **vast majority** of mentally retarded people[21]. This ultimate extension of the special master's reasoning is a fact which is simply not true, cannot be proven, and can be **disproven** with resort to any honest scientific inquiry. No authority **anywhere** would extrapolate Maggie's pre-shot head size into a 90% chance for mental retardation.

### E. The Decision Appealed Herein.

The United States Court of Appeals for the Federal Circuit reversed, ruling unanimously that Maggie was entitled to compensation in this case. The Court held first that Maggie had suffered a Table Injury – an encephalopathy which manifested itself in the form of seizures occurring within the Table time after vaccination. Pet. App. 6a-7a. The court indicated

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[19] Sells, C.F., "Microcephaly in a Normal School Population," Pediatrics, Vol. 59, No. 2 (February 1977). The study notes a paucity of research regarding microcephaly in normal populations, and cites Nelson and Duetschberger (Dev. Med. Child Nuerol. 12:487, 1970) as a source of a 50% risk figure.

[20] As graphically demonstrated by the chart in the Joint Appendix at page 65, Special Master Baird adopted a definition even looser than the government's expert.

[21] See the Argument set forth in the Brief in Opposition to the Secretary's petition for *certiorari*, September 30, 1994, at section I, subsection A, entitled **"Maggie Whitecotton's So-Called State of 'Microcephaly' Prior to the Shot Has No Medical Significance."** Therein, Respondents conclusively demonstrate that the Special Master's statistical analysis is scientifically invalid.



that because Maggie had shown a Table Injury, she was entitled to "the benefit of the Act's presumed causation," Pet. App. 7a, and the burden was on the government to prove that Maggie's injuries were caused by "factors unrelated" to the vaccine. *Ibid.*

The Federal Circuit then went on to hold that the government had not met its burden of proof, for two separate and independent reasons. First, the Court applied the statutory provision that a "factor unrelated" cannot include any "idiopathic" condition. Pet. App. 7a, citing 42 U.S.C. § 300aa-13(a)(2)(A). An "idiopathic" condition is one of unknown cause, and all parties below agreed that the cause of Maggie's microcephalic condition was unknown. The Court below cited its prior decision in *Koston v. Secretary, Department of Health and Human Services*, 974 F.2d 157 (Fed. Cir. 1992), which discussed this provision in detail. *Koston* and its progeny have held that such preexisting conditions as Rett Syndrome and Sudden Infant Death Syndrome (SIDS), which have no known cause, cannot defeat Table Injury claims.

The court below also held that the government had not met its burden of overcoming a Table Injury because it had relied upon pure "speculation" that Maggie's pre-existing microcephaly caused her current condition. Pet. App. 8a-9a. The court indicated that at the hearing below, the government called only one expert, Dr. Owen B. Evans, who "could only speculate that Maggie suffered a brain injury at some time before she received the vaccine in August 1975." *Id.* at 8a. The lower courts had erroneously adopted this speculation of Dr. Evans, undercutting the key presumption Congress had placed in the Act for Table Injury cases. *Id.* at 9a. The Federal Circuit concluded that a Table Injury presumption of causation could not be overcome by:

> "speculative or hypothetical matters or explanations" of alternate causation; under the Act, a Table Injury must be presumed vaccine-related unless ***demonstrated to arise*** from "other defined illnesses or factors." *Ibid.* (emphasis added) (citation omitted).

## SUMMARY OF ARGUMENT

The Court in this matter should honor its traditional and appropriate hesitation to re-write legislation in the name of interpretation. The critical aspect of this case is the ***legal*** definition of the quasi-medical terminology of the Act.

And so a primary task in making sense of this appeal is to compare the Act, its language and intent, with the substantive basis of the special master's erroneous Decision. One great problem associated with this case (and many cases in the Office of Special Masters) is the refusal of the Secretary or the court to recognize that "acute complications **or** sequela[22]" of encephalopathies are Table Injuries also, with no time limit applicable for their manifestation. Thus, there was a violation of the statutory presumption of compensability where the special master looked for cause and effect between the seizures and the sequela of encephalopathy, that is, Maggie's current condition.

The specific doctrine[23] which was applied to defeat the claims of Maggie Whitecotton at the trial level violates the clear will of Congress as embodied by the "no-fault" National Childhood Vaccine Injury Compensation Program.

The statutory application of the Court of Appeals below – not its first, nor its latest, where the same issue is presented – pronounces a badly-needed correction.

The Secretary of Health and Human Services and her *amicus curiae* ally participated in the legislative process, and

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[22] As a matter of proper understanding, "acute" does not modify "sequela." A "complication" is by its nature acute, while a sequela is chronic. Maggie Whitecotton's cerebral palsy is an **undeniable** sequela of an encephalopathy. So is retardation.

[23] See the recitation by Judge Turner at Pet. App. 21-22a and discussion by the special master from 36a through 43a. The *Misasi* rule requires a petitioner in a Table "significant aggravation" case to prove that the child would **not** have developed the same ultimate condition, absent the Table-time encephalopathy. This repudiates the express statutory provision of 42 U.S.C. § 300aa-14 (a) I E which lists complications and sequela of DPT encephalopathies as Table illnesses – of equal dignity to the initial encephalopathy or seizure disorder – "for purposes of receiving compensation under the Program."



predicted the result below as a consequence of the specific language of the Act[24]. Yet, the Secretary vigorously protests her statutory burdens and the statutory limitations on her defenses.

Both pillars of the Secretary's appeal will crumble in the light of scrutiny. The Secretary invokes "interpretation" without showing the presence of ambiguity. Her resort to indications of congressional intention is limited, secondary, selective and misleading. And the Secretary would interpret the Act in a manner which rejects its explicit categories.

The burden is the key. The statute imposes a burden of showing "significance" for an aggravation case. But the "residual seizure disorder" – an "onset" injury – is significant as a matter of law. Thus, too high a burden may be imposed on a child like Maggie, and it follows that an even higher – well nigh **impossible** – burden is placed on petitioners in legitimate significant aggravation cases.

The second argument invokes but does not embody "logic." The Secretary avers that her expert's hypothetical preexisting condition – supposedly shown by Maggie Whitecotton's small head – makes it "logically impossible" that the vaccine could have injured her. But there is unrebuttable evidence – medical test results – which documented an acute brain injury at the time of vaccination[25].

Similarly, the *amicus curiae* brief presents an illogical policy argument. The assertion will not withstand scrutiny that the Court of Appeals' construction of the statute is "medically unworkable." There may be little reason to debate

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[24] Petitioners will demonstrate, *infra*, numerous statements of position by the Secretary and its allies in the medical establishment, made during the legislative process. The Petitioners and the Justice Department clearly foresaw the consequences of the Act in its final proposed form, which they now lament. Before passage, the **same** lament was, "this is what will happen if you pass the Act this way." Now, it is disingenuous for the Petitioners to urge "If you **enforce** the Act this way, this is what will happen." They should not be heard to say that the Act does not mean what they **know** it says, and **said** it meant.

[25] See, *e.g.*, the letter from Dr. Bustion to counsel, JA at 63-64, discussing acute demylinating changes in CSF.

whether or not "idiopathic[26]" is broad or narrow; the Court should recognize and hold that the Secretary may not look beyond the **allowable** statutory concepts for "factors unrelated." Unless there is **documentable** evidence of **actual** causation by "infections, toxins, trauma, or metabolic disturbance," the inquiry is at an end. It is not a material dispute for trial where the Secretary goes outside the statute in the defense of an obvious "Table" case[27].

The Table time reaction **is in fact** the "first" manifestation of the "injury, illness, condition, disability or death" which the Act regards as a vaccine injury. One cannot aggravate that which is not already manifested by pain, illness or disability.

The only way an alternate **actual** cause can truly be shown is with reference to identified, temporally-significant **exposure** to outside agents. The *amicus* even admits that "where an event frequently associated with neurologic damage is known to have taken place, it cannot be

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[26] In point of fact, the Federal Circuit itself used a narrow definition of the word. Reviewing a general dictionary, we find the following:

> "**id-i-op-a-thy** . . . *n. Medicine.* **1.** A disease of unknown origin or cause; a primary disease. **2.** A disease for which no cause is known. – **id-i-o-path'ic** *adj.*" *The American Heritage Dictionary of the English Language* (1978)

In *Stedman's Medical Dictionary* (25th Ed.) we also find,

> "**idiopathic** . . . Idiopathetic. **1.** Agnogenic, denoting a disease of unknown cause. **2.** Denoting a primary disease.
> * * *
> "**primary** . . . **1.** The first or foremost, as a disease or symptoms to which others may be secondary or occur as complications."

[27] The AAP seems to perceive that the policy to encourage vaccination is thwarted by Table Case no-fault compensation. They must fear that the concrete experience under vaccine compensation law will make the DPT vaccine appear to be a defective product; they also fear that children with neurologic disorders will not be vaccinated as "recommended." *Amicus* brief at page 15. But the counterargument certainly avails. Concerned parents will most **certainly** hesitate to vaccinate their children if the government refuses to be responsible for apparent vaccine injuries.



predicted with any degree of certainty that the child in question was injured . . . " *Amicus* brief at 14[28].

Upon whomever is placed the burden, is placed the effect of practical reality: nobody can predict what will happen in the individual case. But to enforce "no-fault" compensation this Court must require that the Secretary, under the statute, document and explain the presence and import of an alleged preexisting condition. "Microcephaly" – a non-specific diagnosis – does not qualify under the statute, either as a preexisting condition or as an alternate cause. Nor does the record support the assertion that Maggie Whitecotton's head size had **any** medical significance to an "onset" case.

It should be the holding of this Court that to show a preexisting "encephalopathy," the Secretary must demonstrate an illness which meets the **statutory** definition of encephalopathy. It is not proper that the Secretary be allowed to ignore the fact, in the case of Maggie Whitecotton, that a small head is not a symptom[29] of disease.

It is necessary that the Court be exposed to the legislative process as an indicator of legislative intent. More importantly, it is necessary that this court review the legal reasoning and doctrines which place **all** Vaccine Act petitioners at a disadvantage. Only with a clear understanding of the way in which the Vaccine Court ignores and violates the express terms and spirit of this important legislation will this Court be able to enforce the statute, deliver justice to Maggie Whitecotton, and in so doing promote the important policies which underlie the Act.

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[28] The *amicus* also acknowledges that individual children may be "stronger or weaker than most." *Ibid.* This is **not** an argument for abandoning Table treatment of injuries.

[29] The "finding" of a preexisting encephalopathy is to be reviewed *de novo*. It is a question of law, of whether or not the condition meets the specific legal definitions of encephalopathy under 42 U.S.C. § 300aa-14 (b) (2) and (3).

## ARGUMENT ONE: THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT MUST BE "INTERPRETED" TO SAY THAT MAGGIE WHITE-COTTON IS CLEARLY ENTITLED TO THE PRESUMPTION OF COMPENSABILITY UNDER THE PROVISIONS OF THE INITIAL VACCINE INJURY TABLE.

### A. The Petitioners' Statutory Burden.

> "The Vaccine Act . . . tries more quickly to deliver compensation to victims, while also reducing insurance and litigation costs to manufacturers. The Act establishes a special claims procedure involving the Court of Federal Claims and special masters (a system we shall call the "Vaccine Court.") ***A person injured*** by a vaccine may file a petition with the Vaccine Court to obtain compensation (from a fund financed by a tax on vaccines). He ***need not prove fault. Nor***, to prove causation, ***need he show more than that he received the vaccine and then suffered certain symptoms within a defined period of time***." BREYER, C.J., in *Schafer v. American Cyanamid Co., supra,* 20 F.3d at 2-3 (1st Cir. 1994) (Citations omitted, emphasis added.)

The statute explicitly defines the Petitioner's burden in terms of the elements of the Petition. In the Act at 42 U.S.C. § 300aa-13 (a) (1) (A) and (B), Congress incorporated by reference the elements of a Petition. The plain statement in the statute, the "general rule," (see full text, Pet. Br. page 3) is that " . . . ***Compensation shall be awarded . . . if . . . the petitioner has demonstrated . . . the matters required in the petition*** and . . . (t)here is not a preponderance of the evidence that the illness, disability, injury, condition, or death[30] described in the petition is due to factors unrelated to the administration of the vaccine described in the petition."

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[30] It is significant that the Act **repeatedly** describes vaccine injury with this combination of terms, **all of which denote the absence of good health.**



The holdings of the lower courts, *e.g.*, in placing a burden to apportion between even a latent "preexisting condition" and the apparent sequela of the acute illness described in the petition, are therefore suspect.

### B. The Improper Burden of Proof Imposed.

The doctrine which infects the judgment below was created from whole cloth by Special Master Paul Baird, in the case of *First Commercial Bank v. Secretary of DHHS*, Case No. 90-537V (Cl. Ct. Special Master, Feb. 25, 1991). Then the doctrine was adopted wholesale by Special Master LaVon French, in the case of *Misasi v. Secretary of DHHS*, and when, as it inevitably will in almost any case, it foreclosed the petitioner from recovery, it was reviewed by the Claims Court, and upheld in *Misasi v. Secretary of DHHS*, 23 Cl. Ct. 322 (1991). The doctrine was promulgated in these cases **without any citation of supporting authority.** It is now frequently referred to in vaccine practice as the "*Misasi* rule."

The *Misasi* formulation of the rule is found at 23 Cl. Ct. 324, and is repeated verbatim by Judge Turner herein (Pet. App. 21-22a):

> "To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's preexisting condition, (2) assess the individual's current condition after the administration of the vaccine, (3) ***predict the*** individual's ***condition had the vaccine not been administered***, and (4) ***compare the*** individual's current ***condition with the predicted condition*** had the vaccine not been administered." (Emphasis added.)

In simple terms, the *Misasi* doctrine is a repeal of the presumption of causation which is the central feature of the no-fault Vaccine Act compensation scheme. In terms of more complex legal analysis, the doctrine is a confusion between medical cause and legal cause, an aberration in the law of compensation. That is, compensation law has **always** found

legal cause in the concepts of "triggering" or "lighting up," and the Vaccine Act embodies those concepts in its definition of injury as being an ***association*** between the vaccine and the disability in question. While Congressional intent clearly is to dispense with difficult causation problems, the thrust of the *Misasi* doctrine is to require proof of actual causation before these petitioners, despite "Table Injury," can recover. The absurdity lies in the fact that almost any vaccination which implicates the *Misasi* doctrine would have been, by definition, contraindicated, had the so-called preexisting condition been recognized at the time.

The *Misasi* doctrine has resulted in an inappropriate confusion, whereby the statutory concept of "factors unrelated to vaccine" is extended to embrace the not only idiopathic disorders, but also the individual weaknesses of children which may make them susceptible to vaccine injury. These weaknesses in latent form prior to immunization are being improperly equated to preexisting encephalopathies, and parents are required to follow incorrect significant aggravation doctrine in "onset" cases. Parents face the same actual causation burden in legitimate significant aggravation cases.

Thus, the parents of the susceptible child who is outwardly completely healthy at the time of immunization must nonetheless speculate to predict **fully at their own risk,** whether to be confident in administering the shots. If there is an injury, there is no relief. The child with a predisposing disorder must **prove** that it would not have become serious. This he cannot do.

The articulation of the *Misasi* doctrine is a retrenchment, and a retreat from at least five decades of modern doctrine. The idea that an injured party must both qualify and quantify a preexisting condition, even if it is completely latent, is completely unique in the compensation law of modern jurisprudence[31]. Moreover, the doctrine is contrary to the well-developed common law of torts, which imposes the burdens on the defense, and requires a specific sequence of inquiries,

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[31] See the rendition of compensation law in Arguments Four and Five, *infra.*



even where the preexisting condition is already symptomatic. *See*, Sections 433A and 433B of the Restatement (Second) of Torts.

*Misasi* undermines a major purpose of the Vaccine Program, which is to foster confidence and participation in the mandatory childhood immunization effort. Without the certainty of compensation, the "speed and reliability with which the petitioner can expect judgment," Congress recognized that "the compensation system would work an injustice on the petitioner." H.R. 99-908, page 17, USCCAN (1986) page 6358.

Unless all children, including predisposed children, are presumed to be injured, the purpose of the Act is frustrated. Clearly, the Table creates the same presumption for causation in significant aggravation cases as it does for "onset" cases. All that is required is to demonstrate the illness in Table Time which the Act envisions. "Significant aggravation" must be **written back into** the Act.

The *Misasi* rule might just as truly be termed the "*Whitecotton*" rule, if the special master's Decision were to be reinstated herein. But by any name, it is totally at odds with the statutory scheme. The *Misasi* rule should be forcefully repudiated by this Court.

## ARGUMENT TWO: THE STATUTORY CONSTRUCTION URGED BY PETITIONER SHOULD BE DISFAVORED BECAUSE, IF ADOPTED, IT WOULD PRODUCE EFFECTS THAT THE STATUTE WAS INTENDED TO DISCOURAGE.

Petitioner's argument would deny Maggie Whitecotton compensation and leave her no further recourse except in the tort system. Under the law, her right to sue the vaccine manufacturer in tort is preserved. See 42 U.S.C. § 300aa-21(a)(2).

The two principal purposes of this statute, however, were to "protect the adequacy of the Nation's supply of vaccines" and to "compensate those children who are injured by side effects or reactions to those vaccines." Congressional Record,

October 17, 1986, H. 11589 (daily ed., statement of Rep. Waxman upon final passage.)

Both of these purposes would be thwarted by the adoption of construction of the statute urged by the Secretary and her amicus. Maggie and others similarly situated would be left with no alternative, but to initiate tort litigation; this is what the Act sought to discourage by making available no-fault compensation.

Under these circumstances, such an interpretation should be disfavored. Only if the plain meaning of the Act compels such a result should the Court consider adopting a statutory construction which is plainly at odds with the stated policy goals to be achieved by the Act.

This is not such a case. In this case, the plain meaning of the law would further these main underlying purposes, and result in compensation for Maggie Whitecotton.

## ARGUMENT THREE: THE STATUTE IS UNEQUIVOCAL AND CLEAR THAT "FACTORS UNRELATED" MAY NOT BE IDIOPATHIC, HYPOTHETICAL, OR SPECULATIVE.

### A. The Secretary Improperly Seeks to Change the Initial Vaccine Injury Table.

The table of injuries set forth at 42 U.S.C. § 300aa-14 has one aspect not yet emphasized in these proceedings. It is the "***Initial*** Vaccine Injury Table." (Emphasis added.) Because there is a specific design for the way the Table may be changed, any debate about the incidence of "real" vaccine injuries, or the policy concerns raised by the *Amicus*, are to be addressed under the Act itself. The Courts should not be involved.

At 42 U.S.C. § 300aa-2 (a) (1) the Act contemplates research on vaccines, as more fully amplified upon in a note to 42 U.S.C. § 300aa-1. As clearly set forth at 42 U.S.C. § 300aa-14 (c), (d) and (e) the Table may be amended by the Secretary, with input from the Advisory Commission on Childhood Vaccines. The Secretary may also recommend changes in the Table to Congress. But the presumption of



compensability arising from the Table is to be honored in the interim:

> "The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information . . . ***Until such time***, however, ***the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.***" (emphasis added) H.R. 99-908, page 18, *reprinted*, USCCAN at 6359 (1986)

Research called-for by the Act, with respect to DPT, has been completed. Certain of that research is even cited by the *amicus* in its brief at page 15, footnote 41. But the picture is not whole without "DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis," National Academy Press, 1994. Therein, the Institute of Medicine concludes at page 11:

> "* * * ***the balance of evidence is consistent with a causal relation*** between DPT and the forms of chronic nervous system dysfunction described in the (National Childhood Encephalopathy Study, commonly referred to as the "NCES[32]") in those children who experience a serious, acute neurologic illness within 7 days after receiving DPT vaccine."

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[32] Originally, the IOM was critical of causation inferences being based upon the NCES. With its May 2, 1994 report, it changed its tune. Thus, the IOM has finally verified the basis of the statutory presumptions set forth in the original language of the Act. At trial herein, the government's expert implied, speaking of the "British study," that the NCES meant nothing, and maintained that there is no evidence to support the concept of permanent injury by vaccine reaction.

**B. The No-Fault Aspects of the Vaccine Compensation Statute Are at the Heart of Legislative Intent.**

> "Respondents have . . . mounted defenses incompatible with a no-fault system of compensation." – Congressional criticism stated in H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 513, *reprinted*, USCCAN 1989, 3018, 3116.

The opinion in *Schafer v. American Cyanamid, supra,* notes that the Act was passed when *inter alia*, injured persons complained about the uncertainty, delay and cost[33] of tort litigation. Meanwhile potential tort defendants complained of litigation expenses, occasional large recoveries, and the increased cost of doing business. *Id.*, 20 F.3d at 2.

That the Vaccine Act is a "tort reform" is clear. (See the comments of the House Energy and Commerce Committee in House Report 99-908, pages 4-7, "Background and Need for Legislation"). In the long process during which this type of legislation was under study, number of parties, including the Department of Health and Human Services and the American

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[33] A number of Legislative proposals were actively debated. The Vaccine Injury Table was a central feature in S. 2117, introduced by Senator Hawkins (R. Fla.) and debated in 1984. *See*, S. Hrg. 98-1060, "National Childhood Vaccine-Injury Compensation Act," Hearing before the Committee on Labor and Human Resources, United States Senate, 98th Cong. 2nd. Sess., May 3, 1984. (The record of this proceeding will hereinafter be cited as "1984 Senate hearing, page ___.")

The Table was set forth again in S. 827, introduced by Senator Hawkins (R. Fla.) and debated in 1985. *See*, S. Hrg. 99-222, "National Childhood Vaccine Injury Compensation Act Of 1985," Hearing before the Committee on Labor and Human Resources, 99th Cong. 1st Sess. July 18, 1985. (The record of these proceedings will be cited hereinafter "1985 Senate hearing, page ___.")

After S. 2117 and S. 827 were killed, in the presence of strong opposition from the executive branch, the AMA and the vaccine manufacturers backed, respectively, H.R. 1780 and H.R. 4777. These bills were debated along with H.R. 5184, in 1986. None of these bills passed, but all contained the Table. Their tort reforms and disregard of such issues as at-home care caused them to be unacceptable to the Dissatisfied Parents Together. *See*, generally, Serial No. 99-158, "Vaccine Injury Compensation," Hearing before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, United States House of Representatives, 99th Cong. 2nd Sess., July 26, 1986. (The record of these proceedings will be cited hereinafter as "1986 House hearing, page ___.")



Medical Association, sought to preempt all rights of petitioners to sue vaccine makers in court. DHHS was among the first seeking to provide this compensation program as an **exclusive remedy** for vaccine injuries. For instance, in his testimony before the Senate Committee on Labor and Human Resources, Dr. Edward Brandt (Assistant Secretary of Health, DHHS) stated,

> "There are numerous additional problems with the program that (Senator Hawkins' bill) would establish, and I will mention some of them. The proposed program does not represent an exclusive remedy; individuals may choose whether to pursue the tort system or the compensation system. This provision is inconsistent with one of the major stated purposes of the bill, which is to relieve the pressure of litigation on vaccine manufacturers." 1984 Senate hearing, page 18.

But consistent with the early principles[34] presented by Dissatisfied Parents Together, Congress chose to solve the problem by making the Program an **attractive** alternative to the tort system, one which parents would **want** to pursue in lieu of the tort system.

On one hand, it is true that pediatricians and manufacturers are not **completely** immune under the Act. But then again, the Program will require the parents of Maggie Whitecotton to spend over ***five years*** in the pursuit of justice for their child.

The immunity provided to pediatricians and manufacturers is a clear parallel to the immunity classically provided to employers by Workmens' Compensation. Liberal interpretation of compensation legislation, and broad coverage, is

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[34] Principle No. Three, as set forth in the testimony of Jeffrey H. Schwartz, President, Dissatisfied Parents Together, stated:

> "The bill must not restrict in any way a parent's (or child's) right to sue under existing law. The choice as to whether to sue under existing law or to seek this new form of compensation should belong entirely to the parents." 1984 Senate hearing, pp. 49-57.

the trade-off for such immunity[35]. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 667 F.2d 908, 916 (10th Cir. 1981).

While it is true that a typical workmans' compensation statute provides the employer more "consideration" in the bargain, because it provides full immunity and completely prohibits the resort to civil actions, this does not mean that the injured child has less right to consideration in this system. The injured worker knowingly and voluntarily exposes himself to the hazards of the workplace, and gets **paid** to do it. But the child to be vaccinated has no choice in the matter. He is doing his "duty" for the greater good, and could be killed in action. And his parents know that he can't be allowed into school without enduring the unconsented-to insult of the shot, an imposition upon the child that would constitute a battery at common law. And so the Act is fully as much a trade-off to be enforced, such that apparently injured children should be compensated without regard to fault, no less than the injured worker under the many compensation systems which are in place in this country.

### C. The Secretary and the Department of Justice Would Contradict Their Own Statements in the Legislative Process.

While it is not the purpose of the Respondents to advocate that this court "search out" the intent of Congress, Respondents submit that such an exercise will completely refute the assertions of the Secretary and her *amicus*. The Justice Department and the Department of Health and Human Service originally opposed enactment of the Act on the

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[35] Denial of compensation in cases like Maggie's is a threat to the manufacturers. Denying compensation in "significant aggravation" cases is likewise a threat to pediatric medicine. Two of the three petitioners in the triad of special master cases which led to *Misasi* decided to pursue a civil remedy, without even motion for review. (Source: telephone calls with petitioners' counsel.) Denying compensation to a child whose shots were somehow ill-advised will clearly promote malpractice cases. And it especially makes no sense that "significant aggravation" treatment should be denied to the apparent victims of the predicted response to a contraindicated shot. The problem is doctrines which place no real burden on the Secretary, and, conversely, require petitioners to prove causation.



ground that it would create a strong presumption of causation by vaccination. No less than five examples of this opposition are found in the legislative history.

Thus, on October 18, 1986, in the Congressional Record, S. 17344-48, statements of Senators Hatch, Quayle and Dole voice Justice Department and White House opposition to the vaccine compensation bill.[36]

On October 3, 1986, a letter was written from the Assistant Attorney General, Office of Legislative and Intergovernmental Affairs, United States Department of Justice. Addressed to Peter W. Rodino, Chairman, House Committee on the Judiciary, the letter opposed enactment of H.R. 5546 – the text of which was grafted onto S. 1744 (1986), which was enacted. Then on October 7, 1986, a letter was forwarded to Speaker of the House, Thomas P. O'Neill, from Secretary of DHHS Otis W. Bowen, M.D., opposing the final bill. *Inter alia*, the letter voiced opposition to the legislation because of the "table of compensable injuries and interpretive provisions."

Years before the legislation was reported out of Committee, the Secretary and the Department of Justice were opposed to the very basic concepts embodied by the Act. On the 3rd day of May, 1984, in testimony before the Senate Committee on Labor and Human Resources, DHHS Assistant Secretary for Health, Edward J. Brandt, Jr., M.D., stated:

> " * * * the bill[37] . . . has major weaknesses which make it impossible to support. Of special concern

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[36] By this time, ironically, the American Academy of Pediatrics was in opposition to certain aspects of the bill. *See* Argument Three section D, *infra*.

[37] The Table and Aids to Qualification and Interpretation were **jointly developed by the American Academy of Pediatrics and the Dissatisfied Parents Together.** In 1984, Jeffrey H. Schwartz testified (1984 hearing record pp. 49-57) that the Table embodies another of the ten principles which Dissatisfied Parents Together forwarded to Congress:

> "The bill should contain safeguards to assure that the award of compensation will not depend on proof by the petitioners of (the elements of tort, *i.e.*, product and manufacturer identification, negligence, or defect in manufacture); or disproof of all possible alternative explanations for the child's injuries."

> are the broad list of compensable conditions . . . ***The bill establishes a strong presumption*** that the vaccine is responsible for essentially any adverse condition that happens after immunization unless there is uncontrovertible evidence of other causation." 1984 Senate hearing, pp. 13-15. (Emphasis added.)

The Department of Justice joined the anti-Table bandwagon in 1985. Robert L. Willmore, Deputy Assistant Attorney General, United States Department of Justice, responded to questions from the Senate Labor and Human Resources Committee, stating:

> "While simplification and cost savings are desirable goals, they should not come at the expense of credible decisionmaking. Many of the proposed compensation systems, however, suffer from that flaw. We believe, for example, that attempts to 'predetermine' causation would result in decisions that, while perhaps cheaper to arrive at, may be largely arbitrary and indefensible." 1985 Senate hearing, p. 231.

### D. The American Academy of Pediatrics Cannot Deny That the Table Means What It Says.

At the 1984 Senate hearings, Dr. Martin H. Smith, President-Elect of the American Academy of Pediatrics, spoke "in strong advocacy" of the Hawkins bill. Dr. Smith advocated "as simple justice for children that if injury occurs . . . the public owes to the victim a simple, direct and prompt compensation" (1984 Senate hearing, page 145). In written materials submitted[38] into the hearing record, the AAP stated

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[38] The AAP also filed a discussion of the costs of the Program, and **admitted then** that the compensation to be awarded under the Act would financially benefit the Federal government' social programs. At page 239 of the 1984 Senate hearing record, the AAP states,

> " * * * To the extent that victims choose the legislative route, the vaccine-injury costs, such as medical, education, and training expenses for immunization victims, that presently are paid by entitlement and social programs, will be shifted to the compensation fund, reducing the burden on federal programs."



> "The Academy has spent a number of months negotiating with the parents' group, Dissatisfied Parents Together, to reach agreement on the provisions of this bill. We found they had many strong concerns that went beyond our original concept of the legislation. We came to realize that their concerns were real and based on their difficult experience and they similarly came to appreciate the validity of some of our concerns. We know that there are other interested parties that will speak out on this subject and they should be heard. We are confident that out of these hearings can come an excellent piece of legislation that can improve our management of vaccine injuries." (1984 Senate hearing, page 151.)

Dr. Smith's written testimony stated:

> "While this could be looked upon as simple compensation legislation to take care of another instance of product liability, let me stress that the justification lies in the fact that this is the *only* product, to my knowledge, whose use is required by law. This is a unique situation that is deserving of special remedies." (*Id.*, page 152, emphasis in the original.)

In oral, question-and-answer testimony, Dr. Smith went on to favor adoption of the Vaccine Injury Table, and he stated that "there is some advantage in having it in the legislation. There is incorporated in the legislation opportunity for alterations in the table with additional time and experience." *Id.*, page 255.

Then in 1985, at Senate hearings again, Dr. Smith testified that the AAP had already been eight years advocating a Federal vaccine compensation program. 1985 Senate Hearing, page 321. Dr. Smith stated that the AAP objective was "nothing more nor nothing less than simple justice for the children of this country." *Ibid.* Dr. Smith went on to explain the Table:

> "From the beginning of our advocacy of a compensation system, a prime concern has been to ensure the prompt and equitable compensation of those who are truly injured, but at the same time

sort out those temporally associated events as completely as possible if they could mimic vaccine reactions.

**"The table of injuries, appearing in this legislation, is our attempt to serve that purpose.** It represents the advice of Academy experts as to the types of serious reactions possible from each vaccine and the limits of time that can be reasonably allowed for the appearance of these reactions after each dose.

"It may never be possible to perfectly sort these claims, but we maintain that this type of mechanism can bring us closer to the ideal judgement of the claims, as they will arise.

"We hope that this type of table can be included in the legislation, rather than wait the indeterminate time of rulemaking. The legislation provides a mechanism for modification of the table as experience creates the need." *Id.*, page 323, emphasis added.

Dr. Smith went on to state that in evaluating proposed legislation that the "first and most important criterion" was providing "a better and more prompt form of justice for children." *Ibid.*

Also in 1985, the AAP presented both written testimony and responses to questions from Senator Orin Hatch (R. Utah). In the written testimony, the AAP stated of the Table:

> " * * * With the assistance of our own pediatric epidemiologists and neurologists, and with the concurrence of the parent's group, S. 827 contains a scientifically defensible and equitable table of compensible events . . . which have in the past been demonstrated to have a causal connection to the particular vaccine in issue . . . " (1985 Senate hearing page 330).

In the responses to Senator Hatch, the AAP also defended the Table, denying Administration assertions of inflexibility. The AAP stated that the Table is "a scientifically sound listing of recognized reactions." *Id.* at 335.

Finally, though, as the bill neared enactment, the AAP pulled up short. In testimony reproduced in the record in its



pre-scripted form, Dr. Smith stated that with one exception the Table, supported by expert medical and scientific opinion, should be adopted. This "one exception" was that the Table carried the presumption of compensability to sequela of Table reactions, **and** that the concept of "significant aggravation" was included in the Table (1986 House hearing, page 130). Even then, the Academy had no objection to significant aggravation compensation "unless clear medical evidence indicates otherwise." The Academy suggested an amendment to the provisions affording significant aggravation compensation, which would award it "unless there is persuasive medical evidence that the injury was not caused by the vaccine." *Id.* pp. 130-31.

The Secretary's *amicus*, therefore, as much as the Secretary, cannot assert in good faith that the Table was not enforced in the Court of Appeals **exactly** as Congress intended. And shame upon the Academy, in the case of Maggie Whitecotton, for loosing sight of its major goal in supporting this legislation, of simple justice for children.[39]

### E. The Federal Circuit Consistently Follows the Rule Below, and Correctly Holds That the Government Must Satisfy an "Actual Causation" Burden of Proof.

The Secretary seeks the repudiation[40] of the recent case decision of the Court of Appeals in *Koston v. Secretary of DHHS*, 974 F.2d 157 (Fed Cir. 1992), which sets forth a straightforward reading of the Act:

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[39] The Academy has also, apparently, failed to consider its other goal – shielding vaccine makers and doctors from tort litigation. More, not less, tort litigation would flow from the statutory construction the AAP urges on the court.

[40] The Secretary **advocated Koston** in its brief for rehearing before the Court of Appeals. While she says here that *Koston* is illuminative of "consequences that congress could not have intended" (Pet. Br. p. 33), the Secretary below accepted *Koston*, attempted to distinguish this case, and stated, ***the rejection of an idiopathic alternate cause was well grounded in the Vaccine Act."*** Brief in Support of Rehearing, p. 12.

> " * * * * Section 300aa-13 (a) (2) (A) defines unrelated factors as ***not including*** 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.' Since the word 'or' is used with both the adjectives (idiopathic, unexplained, unknown, or hypothetical) and the nouns (cause, factor, injury, illness, or condition), ***it is apparent that an unrelated factor is not an idiopathic illness***, an unexplained illness, or an unknown cause. As Koston says, 'The statute is plain enough. An "idiopathic" condition, or a condition with an "unknown cause", is not a "factor unrelated" to the administration of the vaccine.' " *Id.*, 974 F.2d at 160, emphasis added.

The *Koston* court recognized that "(o)ur task is purely one of statutory interpretation." *Id.*, 974 F.2d at 160. The court acknowledged that "Section 300aa-13 (a) (1) (B) of the Vaccine Act bars compensation if there is 'a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine.' " *Ibid.* The failure of the Court of Federal Claims on review below, and the consistent failing of the special masters, never more evident than in this case, is to recognize just how limited and narrow Congress intended the search for alternate cause to be.

The *Koston* decision as quoted above from 94 F.2d at 160, *supra* explicitly stands for the proposition that the use of the word "or" confines inquiry; if it requires that the special master observe the entire list of etiologies which cannot be factors unrelated, it follows that the special master must follow and be limited by the list which can.

Moreover, in *Koston*, at page 161, the Court of Appeals states:

> "By the plain words of the statute, we have an unknown cause and seizures occurring within three days, the period the Vaccine Injury Table sets for recovery. 42 U.S.C. § 300aa-14. ***That is the end of our inquiry***, although we are also satisfied that this interpretation is consonant with the purpose of the statutory scheme . . . " (Emphasis added.)



Another decision from the Court of Appeals, *Knudson v. Secretary of DHHS*, 35 F.3d 543 (Fed. Cir. 1994) furnishes an important source of proper interpretation of the Act and its language.

The Secretary and her *amicus* ally cite[41] *Knudson* for the proposition that the statutory concept of "idiopathic" is not to be taken literally. The Academy states, "the court held that the government could defeat a compensation claim by offering proof of an alternative cause of injury – there, a viral infection – although the cause of the (viral) infection was unknown." This is a word game. The cause of a viral infection is a **virus**. The implication that a virus is "idiopathic" is unsupportable. The Court correctly so held.

Moreover, – and this is the key – an infection is within the statutory list of factors unrelated which **is** allowable to rebut the presumption of compensability in a Table case. Why, then, did the Secretary not prevail in *Knudson*? It is because she could not **prove** that the viral infection caused the encephalopathy.

Knudson stands for the eminently correct proposition that the government's burden to prove alternate causation, once a Table injury has been proven, is the same as an off-Table petitioner's burden to prove actual causation. *Id.*, 35 F.3d at 548-549 ("proof of actual causation in fact generally requires 'proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury . . . ' [citations omitted]. . . . thus the government may defeat a petition with a theory of viral infection so long as it proves that there was in fact a viral infection ***and that the viral infection 'in the particular case [was] . . . principally responsible for causing the petitioner's illness . . . '*** " Emphasis added.) The issue on review was one of law, *i.e.*, the legal sufficiency of the actual causation showing. And the Court rejected **exactly** the same theory of causation as Dr. Evans forwarded herein, namely that because viral infections (or "chronic brain syndrome") is so much more common than vaccine injury, then viral infection "had to be the cause." *Id.* at 550.

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[41] Secretary's Brief at 28, 29-34, Academy's Brief at 9-11.

Finally, the *Knudson* court correctly enforced the Table presumption of causation of "sequela." At page 550, the court stated, "there is no requirement under the Vaccine Act that petitioners prove that DPT caused symptoms or injuries ***other*** (emphasis in original) than the Table injury or the injury complained of."

Although it is the rule that when an erroneous standard prevails at trial, it is normally not for the appellate court to decide the case (but rather to remand), this is not the case where only one result can follow. See, *Pullman-Standard v. Swint*, 102 S.Ct. 1781, 456 U.S. 273, 72 L.Ed.2d 66 (1982). This Court should affirmatively rule in Maggie Whitecotton's favor.

## ARGUMENT FOUR: MAGGIE WHITECOTTON'S CASE DOES NOT BRING INTO PLAY THE STATUTORY CONCEPT OF "SIGNIFICANT AGGRAVATION."

### A. There Must be Preexisting Symptoms Before There is a "Preexisting Condition."

It is simple with reference to the Act to demonstrate the absurdity of the government's characterization of a certain size small head[42] in any event as a "preexisting condition." It is shown by the fact that virtually no compensation would be available for a person with "symptoms" identical to Maggie's state before her third vaccination. She had **no** neurological[43] manifestations.

That is, 42 U.S.C. § 300aa-15 (a) contains the shopping list of remedial measures, the cost of which are used to calculate the compensation. None of these address the problems of the person with a small head. Such a person **has no**

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[42] In the course of the petitioner's arduous but successful litigation in the case of *Ciotoli v. Secretary of DHHS*, 18 Cl. Ct. 576 (1989), the Department of Justice argued that the child's head was **too large** for him to be normal.

[43] Quite clearly the head size itself is not the type of "condition" which the Act refers to as neurological. See, *e.g.*, the description of encephalopathic symptoms in § 300aa-14 (b) (3) (A), and note the requirement for ***significant injury*** to or ***impairment of function*** of the brain, which, like "abnormality," must be ***acquired***. (Emphasis added.)



**problems.** The Act contemplates compensation for services which are required when a child is developmentally disabled. It only follows that something is not a preexisting condition which makes a child different, if the child is **not** in need of such services.

Simply put, "significant aggravation" as used in the statute requires a preexisting **disability**. Maggie Whitecotton had no health problems of a compensable variety for "deterioration," nothing to be made "worse," and no disability or pain to be made "markedly ***greater***." That which does not **exist** cannot be made "greater." *See* the definition of significant aggravation at 42 U.S.C. § 300aa-33 (4) (Pet. Br. p. 6). This point – that a condition must be already clinically active to be "aggravated," is made in countless cases from compensation law systems. *See, e.g., Matter of Compensation of Aquillon*, 653 P.2d 264 (Or. App. 1982); *Reynolds v. Ruidoso Racing Assn, Inc.*, 365 P.2d 671 (N. Mex. 1961); *Hoppin v. Industrial Commission of Arizona*, 692 P.2d 297, 304 (Ariz. App. 1984); *Silva v. New England Group, Maremount Corp.*, 444 A.2d 343 (Me. 1982); and *Self v. Starr Davis Co.*, 187 S.E.2d 466 (N.C. 1972).

### B. "Significant Aggravation" Only Applies To Clinical Illnesses.

The Secretary complains in her brief that in the case of *Cepeda v. Secretary of DHHS*, Case No. 90-2664 (Fed. Cl. Spc. Mstr. July 12, 1994) one special master has stated, "significant aggravation 'need no longer be referenced in the resolution of table cases.' " Pet. Br. at 23-24. This interpretation need not be made of the rule below. Rather, the commonsense argument relied upon by petitioners in *Cepeda* was founded exclusively in the statute. The *Cepeda* court, nonetheless, may have the **first** to give a presumption of causation in a true significant aggravation[44] case! The import of *Cepeda*

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[44] Other than the fact that the Table case was one of significant aggravation, the *Cepeda* fact situation is analytically identical to that described by the Federal Circuit in *Knudson*. There was a possible virus infection, but the government could

(or perhaps more accurately, the import of *Whitecotton* **to** *Cepeda*) is merely the enforcement of the concept of "significant." But Congress provided for "significant aggravation" to serve its purpose of promoting confidence:

> "While it is true that some children, because of their physical condition, are more likely to react to a vaccine, vaccine reactions are not completely foreseeable. There is today no "perfect" or reaction-free vaccine on the market. A relatively small number of children who receive immunizations each year have serious reactions to them. But ***it is not always possible to predict who they will be*** or what reactions they will have. ***And since State law requires that all children be immunized*** before entering school, most ***parents have no choice*** but to risk the chance – small as that may be – that their child may be injured from a vaccine." H.R. 99-908, page 6, reprinted at page 6347, USCCAN 1986, emphasis added.

Two completely different scenarios are lumped together by the *Misasi* doctrine, as applied by Special Master Baird at trial below. The first is where a latent disorder (e.g., Tuberous Sclerosis Complex, as in *Costa v. Secretary of DHHS*, 26 Cl. Ct. 866 (1992)) might be seen as "triggered" by a vaccine[45]. The second is where an already symptomatic condition is made, allegedly, significantly worse. In looking at the legitimacy of the doctrine, Worker's Compensation law provides the answer: such "lighting up" is **cause**, not aggravation. *See*,

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not prove that it caused the encephalopathy. The special master, with the evidence seen "in equipoise," (*see Knudson*, 35 F.3d at 550) ruled for petitioners.

[45] See also, *Huber v. Secretary of DHHS*, 22 Cl. Ct. 255 (1990) compensation awarded, Case No. 89-72V, Special Master Decision August 6, 1990, and *Wilson v. Secretary of DHHS*, 23 Cl. Ct. 169 (1991) (appealed on other grounds), compensation awarded, Case No. 89-65V, Special Master Decision January 22, 1991. In these cases, the latent condition of Tuberous Sclerosis Complex was seen as no defense, and the injuries seen as "onset" injuries. Contrary to the new, interim rule of *Costa*, "significant aggravation" should **only** apply, even to TSC cases, where a child has **actually** seized before the shot in question.



*Reynolds v. Ruidoso Racing Association*, *supra*, ("aggravation" implies previous disability, legal cause is the concurrence of the injury and the preexisting factors, statutory requirements of aggravation need not be literally applied). *Accord*, *Hoppin v. Industrial Commission of Arizona*, *supra*, (where there is no preexisting disability, there is no apportionment; the employer "takes his employee as he finds him.") **All** resulting disability, when the preexisting **latent** condition combines with the injury, is "in legal contemplation the proximate result of the industrial injury." *Id.*, 692 P.2d at 304. *See also*, *Matter of Compensation of Aquillon*, *supra*, and *Silva v. New England Group, Maremount Corp.*, *supra*.

## ARGUMENT FIVE: THE COURT OF APPEALS MUST BE AFFIRMED WITH A DECISION WHICH HONORS THE EXPRESS STATUTORY LANGUAGE AND LEGISLATIVE INTENT

The functions of statutory interpretation are to be delineated before an exercise in interpretation is undertaken. To interpret law is to make law. *See*, generally, 2A *Sutherland Statutory Construction* (5th Ed.) § 45.03. Nonetheless, the courts are in the business of statutory interpretation, and **if interpretation is necessary** the government has correctly invoked the all-encompassing standard, "the intent of the legislature." *Sutherland*, *supra* at § 45.05, states that cases setting forth this rule are "so numerous that it would serve no purpose to attempt to cite all of them."

This is not to say that caution is inappropriate. The scholarship on the subject is such as to suggest a prime directive: As stated by Holmes, "we do not enquire what the legislature meant, we ask only what the statute means." *Id.*, at § 45.07, page 31, pointing out the concurring opinion of Justice Jackson in *Schwegman Bros. v. Calvert Distillers Corp.*, 341 U.S. 384, 95 L.Ed. 1035, 71 S.Ct. 745 (1951) and citing to Frankfurter, Some Reflections on the Reading of Statutes, 47 Colum. L. Rev. 527 (1947).

Turning, then, to the question of whether and how a certain word (*e.g.*, "idiopathic") should be construed, we find in Sutherland several principles.

"The policy favoring conventional meanings and general understanding over obscurely evidenced intention of the legislators is supported in the oft repeated premise that intention must be determined primarily from the language of the statute itself. *Id.*, § 45.08, citing *Flora v. United States*, 357 U.S. 63, 2 L.Ed.2d 1165, 78 S.Ct. 1079 (1958). And of course this philosophy is more concretely expressed in the "plain meaning rule," explicated in Sutherland at § 46.01. Throughout Chapter 46, we find the nuances of this rule; nowhere, even in § 46.07 ("Limits of Literalism"), is there support for the notions of interpretation forwarded by the Secretary and her *amicus*, with regard to the concept of "idiopathic." The consideration that should most easily tip the balance in favor of Maggie Whitecotton, and similar petitioners (*e.g.*, Jenna Koston or Debra Ann Knudson), is the principle that each word of the statute should be given effect. *Id.*, § 46.06.

### A. There is No Legitimacy in an "Interpretation" Exercise.

The Secretary seeks two affirmative rulings by this Court, both of which involve statutory "interpretation" or "construction." Ultimately, the statutory interpretation argument which is the very heart of the appeal comes down to the meaning of **only two** separate words. The first of these words is "first," as in "first symptom or manifestation of . . . onset ***or . . . significant aggravation***[46]."

The second of these words is "idiopathic," as in "***factors unrelated . . . does not include*** any idiopathic, ***unexplained, unknown, hypothetical, or undocumentable cause . . .*** "

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[46] 42 U.S.C. § 300aa-14 (a) (emphasis added). Query, if one of the first symptoms in a Table case can be the first symptom in the significant aggravation of a preexisting condition, what more should the Vaccine Court look for, than a child who was hospitalized with seizures? Does not the contemporaneous diagnosis of "immunization encephalopathy" imbue Maggie Whitecotton's seizures with enough legal dignity to satisfy the criteria for "first" symptom of apparent vaccine injury? Should not the burden shift to the Secretary?



"Idiopathic" is the **only** "medical[47]" word in the list of prohibited factors unrelated. But the Secretary wants an interpretation **against** petitioners. She wants the meaning and application somehow limited. With the word "first," the Secretary wants a **strict** application, again, to favor the government and to work against compensation.

It is axiomatic that congress is presumed to have intended the omission of words that it could have carried over from other parts of the same legislation, in order to effect the same meaning. Congress **could** have left the door open to other, non-specified "factors unrelated," by stating that "if an encephalopathy was caused by infections, toxins, trauma, metabolic disturbances **or other factors unrelated**, it shall not be considered a condition set forth in the Table." The failure to include such as the emphasized language in 42 U.S.C. § 300aa-14 (b) (3) (B) must be considered to be intentional. *See, Russello v. United States*, 464 U.S. 16, 23, 104 S.Ct. 296, 300, 78 L.Ed. 2d 17 (1983).

There has been no common-sense discussion of the provisions defining "factors unrelated." No questions have been answered regarding the effect of the **other** limitations on "factor's unrelated." Is not the government defenses of "chronic organic brain syndrome" embraced by the expressions "hypothetical" or "undocumentable?[48]" What type of idiopathic syndrome is **not also** to be regarded as "unknown?" How can the court enforce the concept of "unexplained cause," if it redefines "idiopathic?"

The meanings of the other words of § 300aa-13 (a) (2) (A) are revealing. While not to belabor the point by defining the prefix "un," petitioners would point out that one dictionary meaning of "explain" is "To offer reasons for or a cause

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[47] It should be pointed out that the "medical" concepts of "residual seizure disorder" **and** "encephalopathy" are given broad meanings which are liberal to the concept of finding compensable injury. It would seem curious that Congress would expressly **re**-define such terms, with a broad scope, if – as argued by the Secretary – it **also** "intended" that the word "idiopathic" be interpreted **not** to have the **normal** meaning which would also serve the same end.

[48] The Court of Appeals held the defense to be "speculation."

of; answer for; justify." *American Heritage Dictionary of the English Language* (1978). And the same tome defines "document," the verb, as "to support (an assertion or claim for example) with evidence or decisive information."

Similarly, "hypothetical" carries a definition of "suppositional, conjectural, uncertain[49]." And "unknown" – all but a synonym of "idiopathic" – is defined as "**a.** Not identified or ascertained; **b.** Not established or verified." *Op. cit.*

It is therefore clear that with these five statutory words, in a true sense, Congress stated that it **would not countenance** "idiopathic" factors unrelated. Upon saying this, Congress then reinforced the statement with four more synonymous modifiers. The argument is most specious which regards the Congressional intent as not being to give the word "idiopathic" its normal meaning.

### B. A Condition Affected By Vaccination Cannot Be A "Factor Unrelated To Vaccine."

> "It cannot be said that the development of the disease as a result of the injury was not the consequence which might naturally or ordinarily follow as a result of the injury." 22 Am.Jur.2d 233, *Damages* § 283, citing *Chicago City Railway Co. v. Saxby*, 23 Ill. 274, 72 N.E. 755 (1904).

The concept of "relatedness" has been frequently examined by the courts. As a matter of law, the activity which is the central feature of a compensation plan needs only to have a nexus with the incapacity suffered in order for it to be "related." Therefore, any condition magnified, altered or acted on in any way by vaccination is not a "factor unrelated."

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[49] Lest the Court feel constrained to honor the "factfindings" of the special master because the Court of Appeals did not disavow them, petitioners would point out that it did not **need** to. Because the Court of Appeals correctly decided that the Vaccine Court applied an erroneous standard of law, there was no need to address the factual concerns. But the Petitioners **did** furnish every reason for the factfinding to be rejected, including materials in support of a Rule 60 (b) motion. Many of these materials are included in the Joint Appendix. *Inter alia* these statements of medical fact witnesses specifically refute the misstatements in Maggie's medical records, all of which factors were relied upon by the Secretary's expert Dr. Evans.



Numerous cases have reached the courts in the area of service-connected disability for peace officers, firemen, and other public employees. Only where **no** connection can be shown between employment and disability (even in cases of heart attack, arthritis, tuberculosis, cancer, psychological disturbances, and the like), only where the underlying weakness is seen as the **sole** cause, may the claim legally be rejected. See, generally, the annotations at 85 ALR 2d 1048, 7 ALR 4th 799, and 12 ALR 4th 1158; *see also Bolinger v. Division of Retirement, State Department of Administration*, 335 So.2d 568 (Fla. App. 1976)[50].

Ultimately, the presumption created by "Table Time" under § 300aa-14 is the basis for finding that a condition is "related" to vaccine. It is an illegitimate undermining of the legislation for the Secretary to deny this, and to sponsor a witness who does not believe that vaccine injury is possible. To such an expert as Dr. Evans, **any** condition would be by definition a "factor unrelated" to what the government, his sponsor, insists is a harmless vaccine. This is bias, and renders the opinion valueless. *cf. Bradley v. Secretary of DHHS*, 24 Cl. Ct. 641 (1991). Testimony that a presumed injury "cannot occur" does not rebut a statutory presumption of injury. *Pinion v. Board of Retirement*, 152 Cal. Rptr. 383 (1979 5th Dist. App.); *see also, Bunting v. Secretary of DHHS*, 931 F.2d 867, 873 (Fed. Cir. 1991).

### C. The Vaccine Act Must Be Harmonized With Compensation Law

The Court of Appeals ruling herein is philosophically consistent with the most mainstream elements of American law: The injured party is taken as he or she is found prior to the injury; the burden is not to be placed on the innocent injured party to apportion between the wrongdoer and some other possible cause; to hasten injury is to cause it; to interpret the law is prohibited where its meaning is clear. *A fortiori*, the nature of the Act as a "no-fault" compensation Act calls for this court to affirm the Court of Appeals ruling.

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[50] *Bollinger* also points out that an impact on the compensation fund is an issue for the legislature, and not the courts.

A very instructive Decision, from the Office of the Special Masters, is virtually the only such **explicit** statement in the law of vaccine compensation to thoughtfully consider these mainstream philosophies. Petitioners commend the court to the case of *Costa v. Secretary of DHHS*, Case No. 90-1476V (Cl. Ct. Spc. Mstr. February 26, 1992)[51].

The Secretary refuses to acknowledge that liberal interpretation doctrines from compensation law, or even that **any** doctrines from other compensation laws, were "intended" by Congress for the Vaccine Program[52].

The huge body of American compensation law clearly establishes the reality and compensability in the "lighting up" or "triggering" of latent pathologies[53] and diseases, from diabetes to tuberculosis, from heart disease to congenital back weakness. And compensation law is instructive as to the necessary nexus between the contemplated source of compensable injury (whether it be

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[51] This case was remanded by a Judge of the Claims Court to the special master, on the government's interlocutory appeal, by virtue of the previously-cited *Costa v. Secretary of DHHS*, 26 Cl. Ct. 866 (1992). The case has not been passed upon in the Court of Appeals, although the government announces the intention to appeal. But damages proceedings (the petitioners prevailed both initially and on remand) continue in the Office of Special Masters. For reasons discussed herein in Argument Four, *supra*, Petitioners disagree with the order of remand, to the extent that it requires the application of "significant aggravation" doctrine to the case of a child who was in **perfect** health prior to the shot.

[52] See the discussion at 2A *Sutherland Statutory Construction* § 45.10 (5th Ed.), relating to the concept of "legislative common law." This concept is at the heart of the use of such terms as "no-fault." Legislative bodies have a particular and very concrete scheme in mind when the idea of a "compensation act" comes up. Congress has enacted compensation laws before; this Court has reviewed them all.

[53] The *Costa* cases involve the compensability of vaccine injury in children who are born with the condition known as Tuberous Sclerosis Complex, or TSC. TSC is a condition known to involve mental retardation and seizures, but **never** to involve mental retardation **without** seizures. Approximately two-thirds of the population with TSC are believed to be seizure-free and mentally normal. And permanent vaccine injury is scientifically estimated to be **3000 times more common** in the TSC community than in the "normal" population. Miller, *et al.*, Unreviewed Technical Report, "Parent Reports of DPT Seizure Reactions in Individuals with Tuberous Sclerosis Complex." University of Akron, January 1995. Congress did not give the slightest hint that it did not intend to protect even these children, when it crafted the Act.



employment in general, exposure to certain conditions such as coal dust, or any other subject of compensation legislation) and the ultimate sequelae, in order to qualify for compensation.

Finally, then, Respondents urge the Court to follow the approaches taken in its previous cases which are at the heart of the "interpretation" issues here.

Thus, as in the recent decision of *Brown, Secretary of Veterans Affairs v. Gardner*, ___ U.S. ___, 63 USLW 4035, 1994 WL 687055 (Case No. 93-1128, decided December 12, 1994), this Court should "naturally read" the statutory language, and resolve interpretive doubt in Maggie Whitecotton's favor. *See, King v. St. Vincent's Hospital*, 502 U.S. 215, 220-221, 112 S.Ct. 570, 574, 116 L.Ed.2d 578 (1991), fn. 9.

Here, as in *Good Samaritan Hospital v. Shalala*, 508 U.S. ___, ___, 113 S.Ct. 2151, 2157, 124 L.Ed.2d 368 (1993), the Court must again pronounce that "the text and reasonable inferences from it give a clear answer against the government, and that, as we have said, 'is the end of the matter.' " *Brown, supra*.

As stated by Justice O'Connor, writing for the majority in *Director Office of Worker's Compensation Programs, U.S. Department of Labor v. Perini North River Associates*, 103 S.Ct. 634, 459 U.S. 297 (1983), it has been "long held" that the compensation statute is to be liberally construed, "in conformance with its purpose, and in a way which avoids harsh and incongruous results." *Id.*, 101 S.Ct. at 646.

> "***The system is intended*** to be expeditious and fair. It is also intended ***to compensate*** persons with recognized vaccine injuries ***without*** requiring the ***difficult individual determinations of causation*** . . . " H.R. 99-908, 99th Cong., 2nd Session, pt. 1, page 12, *reprinted* 6 USCCAN 6344, 6353 (1986), emphasis added.

Any resolution of the ambiguity between permissive and mandatory language in the qualifications and aids to interpretation must be accomplished in a manner consistent with the overall purpose of the act; any proper interpretation of the terminology in the Act will most clearly be consistent with compensation for Maggie Whitecotton.

## CONCLUSION

For all the foregoing reasons, the decision of the United States Court of Appeals for the Federal Circuit should be affirmed, and the case remanded to the special master for a prompt determination on compensation owed to Petitioner Maggie Whitecotton.

Respectfully submitted[54],

ROBERT T. MOXLEY*
RICHARD GAGE
GAGE & MOXLEY
623 West 20th Street
Post Office Box 1223
Cheyenne, Wyoming 82003
(307) 632-1112

PROF. PETER H. MEYERS
Vaccine Injury Project
National Law Center
George Washington University
2000 G Street, Suite 200
Washington, D.C. 20052
(202) 994-7463

JOHN S. CAPPER IV
BERRY, CAPPER & TULLEY
P.O. Box 429
Crawfordsville, Indiana 47933

*Counsel for Respondents*
*Counsel of Record

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[54] Counsel appreciate the substantial research and drafting assistance provided by Lynn A. Brazinski, Joanne M. Hatem, M.D., J. Kirk Ogrosky, Heather M. Zimmerman, and Todd P. Forster, all of whom are law students at the National Law Center of the George Washington University.

(7)

No. 94-372



# In the Supreme Court of the United States

OCTOBER TERM, 1994

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DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

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*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

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## REPLY BRIEF FOR THE PETITIONER

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DREW S. DAYS, III
*Solicitor General*
*Department of Justice*
*Washington, D.C. 20530*
*(202) 514-2217*



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# In the Supreme Court of the United States

OCTOBER TERM, 1994

No. 94-372

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

*v.*

MARGARET WHITECOTTON, ET AL.

*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

## REPLY BRIEF FOR THE PETITIONER

1. We have argued in our opening brief (Br. 20-29) that the court of appeals erred in holding that the National Childhood Vaccine Injury Act, 42 U.S.C. 300aa-1 *et seq.* (1988 & Supp. IV 1992), creates a presumption that a vaccine has caused a compensabie condition any time that a child has experienced a symptom or manifestation of that condition during the period set forth in the Vaccine Injury Table, even if the condition had already manifested itself prior to administration of the vaccine. Under the text of the Act, to obtain the benefit of a presumption of causation, a claimant must establish either that the child experienced no symptom or manifestation of the condition prior to administration of the vaccine, or that the child had a preexisting condition that

was significantly aggravated after administration of the vaccine. 42 U.S.C. 300aa-11(c)(1)(C)(i). See also American Academy of Pediatrics Amicus Br. 3-9 (discussing text and legislative history of the Act that supports Secretary's position). Because the special master found that Maggie's head size indicated that she had already suffered an encephalopathy before she received her third DPT vaccination and that the seizures that she experienced afterwards did not indicate significant aggravation of that preexisting condition, the special master and the Court of Federal Claims properly concluded that respondents could not rely on the presumption of causation established by Section 300aa-11(c)(1)(C)(i). See Pet. App. 9a-23a, 30a-43a.

Surprisingly, neither respondents nor their amici attempt to defend the interpretation of Section 300aa-11(c)(1)(C)(i) adopted by the court of appeals in reversing the decision of the Court of Federal Claims and ordering the payment of compensation to respondents. Instead, they attempt to defend the result reached by the court of appeals on numerous other grounds. In particular, respondents contend that: (1) the special master erred in concluding that Maggie had a preexisting encephalopathy (Br. 23, 40-41); (2) the special master erred in his analysis of the issue of significant aggravation (Br. 20 & n.23, 25-27); (3) post-vaccine seizures within the statutory period always create a presumption of causation (Br. 9); and (4) principles established under workers' compensation statutes require compensation here (Br. 41-43). For reasons that differ somewhat from those offered by respondents, Amici Dissatisfied Parents Together, *et al.*, argue that Maggie did not suffer from a preexisting encephalopathy (Br. 9-10) and that the special master erred in his significant aggravation analysis (Br. 13).



The court of appeals did not address any of those contentions. Its holding instead was that a claimant may establish a presumption that a vaccine has caused a child's condition under Section 300aa-11(c)(1)(C)(i) even when that condition manifested itself prior to administration of the vaccine and did not markedly worsen afterwards. Pet. App. 5a-9a. That is the issue on which this Court granted certiorari, and that is the issue it should decide. The Court should not attempt to resolve other issues that were not considered below and that may or may not warrant review by this Court in the future.

Should the Court agree with our submission that the court of appeals adopted an erroneous interpretation of Section 300aa-11(c)(1)(C)(i), it should reverse the judgment of the court of appeals and remand for consideration of any other issues that respondents have properly preserved for appeal. Because an understanding of the additional contentions raised by respondents and their amici may assist the Court in resolving the issue on which it granted certiorari, however, we briefly respond to each of those contentions.

a. Respondents contend (Br. 23, 40-41) that the record does not support the special master's finding that Maggie's head size indicated that she had suffered an encephalopathy prior to administration of the vaccine. In their view, Maggie's post-vaccine seizures were therefore the first manifestation of an encephalopathy. The government's expert testified, however, that Maggie's head size at birth indicated that she was born with a serious brain disorder characterized by impairment of cognition and motor activities. J.A. 45-46. One of respondents' two experts agreed that Maggie's head size indicated that she had suffered a pre-vaccine encephalopathy. He testified that "[s]omething was clearly

happening to the child before [the DPT shot]." Pet. App. 33a. In his written report, that expert elaborated that the growth of Maggie's head had fallen below the normal curve, which "implies a post-partum injury to the brain, at or near three months of age." *Id.* at 34a. Yet Maggie did not receive her third DPT vaccination (which respondents claim was the cause of her injury) until she was almost four months of age. *Id.* at 11a. In light of that evidence, the special master reasonably found that "[w]hether the injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975." *Id.* at 34a.[1]

Respondents assert (Br. 41-43) that, because Maggie appeared healthy prior to administration of the vaccine, the special master erred in finding that Maggie suffered from a pre-vaccine encephalopathy. As the special master noted, however, it is relatively common for children who are microcephalic not to have any other manifestations of brain damage until they have matured to the point at which developmental milestones are missed. Pet. App. 37a-38a. For example, cerebral palsy may not become evident until a child is one year of age, and mental retardation may not become evident until much later. *Id.* at 38a. The special master therefore reasonably determined based on Maggie's microcephaly alone that Maggie was encephalopathic prior to administration of the vaccine.

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[1] Under the Act, that factual finding and the other findings to which respondents object could not in any event be set aside on review by the Court of Federal Claims or the court of appeals unless they are "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. 300aa-12(e)(2)(B) (Supp. IV 1992).



Amici Dissatisfied Parents Together contend (Br. 8-10) that a small head size cannot be a symptom of an encephalopathy as that term is defined in the qualifications and aids to interpretation of the Table set forth in 42 U.S.C. 300a-14(b)(3)(A). That contention is also without merit. Section 300aa-14(b)(3)(A) defines encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A). As noted above, the government's expert testified that Maggie's head size indicated that Maggie was born with a serious brain disorder characterized by impairment of cognition and motor activities, and respondents' expert testified that Maggie's head size was a manifestation of her having suffered a serious injury to the brain prior to administration of the vaccine. That testimony was more than sufficient to establish that Maggie had a pre-existing encephalopathy as that term is defined in the qualifications and aids to interpretation of the Table.

b. Nor did the special master err in his analysis of the issue of significant aggravation. The Act defines a significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. 300aa-33(4). The special master's findings demonstrate that those statutory criteria were not satisfied in this case. Three findings, in particular, are important. First, the special master found that tests performed on Maggie prior to her release from the hospital showed that her condition had not deteriorated as a result of the seizures. Pet. App. 40a. Second, the special master found that after her release from the hospital, Maggie continued to develop at a "slow but sure" pace. *Id.* at 41a. Finally, the special master found that Maggie's neurological problems

gradually manifested themselves, just as they would in a typical case of a child with preexisting microcephaly. *Id.* at 42a. In these circumstances, the special master reasonably determined that Maggie's seizures were not symptomatic of a significant aggravation of her pre-existing encephalopathy. *Id.* at 42a-43a.

Respondents contend (Br. 25-27) that the special master erred in relying on the test of significant aggravation set forth in *Misasi* v. *Secretary of HHS*, 23 Cl. Ct. 322 (1991). That test requires a court to: "(1) assess the individual's condition prior to administration of the vaccine, *i.e.*; evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered." *Id.* at 324. According to respondents, the *Misasi* test improperly requires a claimant to prove actual cause. Although amici do not attack the *Misasi* test as such, they argue (Dissatisfied Parents Together Br. 12-13) that in this case, the special master required respondents to prove actual cause.

The special master did not, however, base his finding of no significant aggravation on respondents' failure to prove actual cause. Rather, he ruled against respondents on their significant aggravation claim because he concluded that "no significant aggravation of Maggie's underlying brain disorder was manifested within three days following the said administration of the DPT vaccine." Pet. App. 43a. Given the special master's findings that Maggie appeared neurologically normal when she left the hospital, that she progressed steadily thereafter, and that her present condition is



typical for a child with congenital brain damage, that conclusion was fully warranted. Maggie's seizures were not symptomatic of either "markedly greater disability, pain, or, illness," or "substantial deterioration of health." 42 U.S.C. 300aa-33(4).

c. Respondents contend (Br. 9) that the court of appeals properly found that Maggie suffered a Table encephalopathy because she suffered seizures within the Table period and an encephalopathy is shown by seizures as a matter of law. That contention is incorrect for two reasons.

First, not every seizure is symptomatic of an encephalopathy. Under the Act, an encephalopathy is defined to mean any "*significant* acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. 300aa-14(b)(3)(A) (emphasis added). Moreover, the Act uses the terms seizures and convulsions interchangeably, 42 U.S.C. 300aa-14(b)(4), and the definition of encephalopathy in the qualifications and aids to interpretation of the Table states that "[a]mong the frequent manifestations of encephalopathy are * * * changes lasting at least six hours in level of consciousness, with or without convulsions." 42 U.S.C. 300aa-14(b)(3)(A). This statutory reference to the combination of seizures and extended loss of consciousness as a frequent manifestation of an encephalopathy would make no sense if every seizure, no matter how brief, were a symptom of an encephalopathy. Accordingly, the Table does not permit a court to assume that every seizure is a symptom of an encephalopathy. The resolution of that issue must be based on the medical evidence in each case.

Second, under the Act, the relevant inquiry is not whether Maggie's seizures constituted a symptom or manifestation of an encephalopathy. Rather, the rele-

vant inquiry is whether the seizures were the *first* symptom or manifestation of the *onset* or *significant aggravation* of an encephalopathy. See 42 U.S.C. 300aa-11(c)(1)(C)(i). Because Maggie's encephalopathy had already manifested itself prior to administration of the vaccine, and did not markedly worsen afterwards, the seizures Maggie suffered in the Table period did not trigger either of the statutory presumptions of causation.

d. Finally, respondents contend (Br. 41-43, 47-49) that they should prevail based on principles that courts have applied in interpreting workers' compensation laws. Those statutes, however, have different language and purposes. Decisions interpreting workers' compensation statutes therefore do not have a bearing on the proper construction of the Vaccine Act.

The cases upon which respondents rely do not assist them here in any event. Those cases hold that when a claimant proves that work-related trauma and a pre-existing condition together cause a claimant's current condition, compensation for that current condition is appropriate. See *In re Compensation of Aquillon*, 653 P.2d 264, 266-267 (Or. Ct. App. 1982), review denied, 658 P.2d 1162 (Or. 1982); *Reynolds* v. *Ruidoso Racing Ass'n*, 365 P.2d 671, 678 (N. Mex. 1961); *Hoppin* v. *Industrial Comm'n*, 692 P.2d 297, 303-304 (Ariz. Ct. App. 1984); *Silva* v. *New England Group, Maremount Corp.*, 444 A.2d 343, 344-345 (Me. 1982). Here, however, the special master found that neither the vaccine nor the seizures Maggie experienced in the Table period contributed to Maggie's current condition. Pet. App. 42a-43a. The cases relied upon by respondents are therefore inapposite.

2. As we have argued in our opening brief (at 29-34), the court of appeals also erred in holding that the



Secretary could not rely on Maggie's preexisting microcephaly to rebut the presumption of causation that arises when the claimant shows that the first symptom or manifestation of the onset or significant aggravation of an injury or condition occurred within the Table period. Pet. App. 7a-8a. The Vaccine Act permits the Secretary to rely on "factors unrelated" to the vaccine to defeat the claim for compensation in that situation. 42 U.S.C. 300aa-13(a)(1)(B). And while the Act precludes reliance on "idiopathic" factors, 42 U.S.C. 300aa-13(a)(2)(A), Maggie's microcephaly is not idiopathic, since it is a defined preexisting condition that logically eliminates the vaccine as the cause of her condition. See Pet. 17-19.

Amici Dissatisfied Parents defend the court of appeals' reasoning on this point in only the most conclusory terms. See Br. 14-18. Respondents offer no defense of the court's reasoning at all. We therefore rely on our opening brief on that issue. Respondents raise two additional points on the "factors unrelated" issue, however, that warrant a response.

a. First, respondents assert (Br. 19) that the court of appeals rejected the Secretary's reliance on an unrelated factor because it concluded that any connection between Maggie's preexisting microcephaly and her current condition was merely speculative. The court of appeals, however, reached no such conclusion. To the contrary, the court acknowledged that the special master's findings that Maggie was microcephalic prior to administration of the vaccine and that Maggie's current condition is typical for a child with microcephaly demonstrated a logical connection between Maggie's microcephaly and her current condition. Pet. App. 8a.

The court of appeals did refer to the Secretary's defense as speculative. Pet. App. 8a. But the court was

simply using the term "speculative" in the same way as it used the term "idiopathic": to refer to the fact that the government was unable to pinpoint the specific cause of Maggie's preexisting microcephaly. *Ibid.* As we have explained in our opening brief (Br. 30-34), the Vaccine Act does not require that kind of proof. To rebut a prima facie case of causation, the Secretary must show by a preponderance of the evidence that a defined factor unrelated to the vaccine caused a child's condition, 42 U.S.C. 300aa-13(a)(1)(B); the Secretary is not required to identify the cause of the cause of the child's condition. As amicus American Academy of Pediatrics explains (Br. 11), "[m]edical literature is replete with acknowledgements of ignorance and uncertainties by eminent researchers as to the causation of birth defects and perinatal injury," and the court of appeals' holding "that only preexisting conditions with known causes can overcome a petitioner's presumption of eligibility, would have serious implications for the nation's vaccine program." See generally *id.* at 11-14, 17-18.

b. Finally, respondents contend (Br. 9-10, 22, 45) that "factors unrelated" to the vaccine are limited in this case to "toxins, trauma, infection or metabolic disturbance." Since Maggie's microcephaly cannot be traced to one of those four factors, respondents argue, the Secretary failed to establish that a factor unrelated to the vaccine caused Maggie's condition. Respondents' contention is without merit.

Section 300aa-13(a)(2)(B) provides that factors unrelated to the vaccine "may * * * include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." 42 U.S.C. 300aa-13(a)(2)(B). The use of the words "may include" rather than "means" shows that Congress intended the four identified factors to be treated as examples of permissible rebuttal, rather than as an exhaustive list. *Pfizer, Inc.* v. *India*, 434 U.S. 308, 312 n.9 (1978); *United States* v. *New York Telephone*, 434 U.S. 159, 169 & n.15 (1977); *Federal Land Bank* v. *Bismarck Lumber Co.*, 314 U.S. 95, 99-100 (1941).



Respondents concede that point, but then contend (Br. 9-10) that the permissive language of that provision is overridden by Section 300aa-14(b)(3)(B), which relates to encephalopathies. That section provides that "[i]f * * * an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table." 42 U.S.C. 300aa-14(b)(3)(B). Nothing in that language compels the conclusion that the four listed factors were intended to be the *only* factors that could defeat a claim for compensation when the petitioner relies on the Table and alleges that the child suffers from an encephalopathy.

The second sentence of Section 300aa-14(b)(3)(B) reinforces the conclusion that the first sentence was not intended to limit the Secretary's rebuttal to the four factors it lists, and thereby to render Section 300aa-13(a)(1)(B) of no effect in cases of alleged encephalopathy. The second sentence provides that "[i]f at the time a judgment is entered * * * it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table." If respondents' construction of the first sentence were correct, the second sentence would have provided that "if an encephalopathy is not shown by a preponderance of

the evidence to have been caused by infection, toxins, trauma, or metabolic disturbances, the encephalopathy shall be considered to be a condition set forth in the table." The quite different tenor and scope of the second sentence as written makes clear that the government can rely on a factor that is not one of the listed four, as long as it is possible to determine by a preponderance of the evidence that the factor identified by the government caused the encephalopathy.

Moreover, Section 300aa-13(a)(1)(B) and Section 300aa-14(b)(3)(B) are structured and operate differently. Section 300aa-14(b)(3)(B) permits the Secretary to show that the identified factors have caused the encephalopathy and that therefore the encephalopathy is not a Table condition in the first place. Section 300aa-13(a)(1), on the other hand, permits the Secretary to show that, even though the claimant *has* made a prima facie showing of a Table injury, "factors unrelated" to administration of the vaccine actually caused the child's condition. Thus, even assuming that the Secretary were limited to the factors identified in Section 300aa-14(b)(3)(B) in showing that an encephalopathy is not a Table condition, the plain language of Section 300aa-13(a)(1) would still permit the Secretary to show that other "factors unrelated" to the vaccine caused the child's condition.

The legislative history confirms that the Act was not intended to operate in a dramatically different fashion in cases of alleged encephalopathies. In explaining the provision relating to encephalopathies, the House Report states that the provision "restates in specific terms the general rule described in Section 2113." H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 19 (1986). The language of Section 2113 referred to in the House Report is identical to the language of Section 300aa-13. H.R. Rep. No. 908, *supra*, at 51-52.



Respondents' more restrictive interpretation also makes no sense. If respondents' view were accepted, it would mean that the Secretary would be unable to rely on genetic conditions, such as Down's syndrome, to rebut a prima facie case of causation. Congress could not have intended that result.[2]

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[2] The Secretary recently issued regulations, pursuant to 42 U.S.C. 300aa-14(c), modifying the Vaccine Injury Table and the qualifications and aids to interpretation in a number of respects. 60 Fed. Reg. 7678-7696. (1995). The new regulations apply only to petitions for compensation filed after March 10, 1995. *Id.* at 7678. Accordingly, they have no application to the present case.

Among the modifications made by the new regulations are revisions to the qualifications and aids to interpretation of the Table with respect to encephalopathy. Under the regulations, a vaccine recipient will be considered to have suffered an encephalopathy "only if such recipient manifests, within the applicable period, an injury meeting the description * * * of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination." 42 C.F.R. 100.3(b)(2). An acute encephalopathy "is one that is sufficiently severe so as to require hospitalization," 42 C.F.R. 100.3(b)(2)(i), and, in the case of children who are less than 18 months of age, is indicated "by a significantly decreased level of consciousness lasting for at least 24 hours," 42 C.F.R. 100.3(b)(2)(i)(A). "Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy," and in the absence of other evidence, "seizures shall not be viewed as the first symptom or manifestation of the onset of an encephalopathy." 42 C.F.R. 100.3(b)(2)(i)(E). A chronic encephalopathy occurs when "a change in mental or neurological status * * * persists for a period of at least six months." 42 C.F.R. 100.3(b)(2)(ii). When the evidence indicates that a child's chronic encephalopathy "is secondary to genetic, prenatal, or perinatal factors," or when "a preponderance of the evidence [indicates] that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic

* * * * *

For the foregoing reasons, as well as those stated in our opening brief, the judgment of the court of appeals should be reversed and the case should be remanded to the court of appeals for review of the judgment of the Court of Federal Claims under the proper legal standards.

Respectfully submitted.

DREW S. DAYS, III
*Solicitor General*

FEBRUARY 1995

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disturbance, structural lesion or genetic disorder is known)," the encephalopathy is not considered a Table condition. 42 C.F.R. 100.3(b)(2)(ii) and (iii).

The regulations also remove residual seizure disorder from the list of conditions associated with the DPT vaccine. 42 C.F.R. 100.3(a).

No. 94-372

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OCTOBER TERM, 1994

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*Petitioner,*

v.

MARGARET WHITECOTTON, *et al.*,
*Respondents.*

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**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

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## AMERICAN ACADEMY OF PEDIATRICS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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STEPHAN E. LAWTON *
ANNE M. DELLINGER
HOGAN & HARTSON
555 13th Street, N.W.
Washington, D.C. 20004
(202) 637-5600
*Attorneys for the Amicus Curiae*
* Counsel of Record

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**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

**AMERICAN ACADEMY OF PEDIATRICS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER**

## INTEREST OF *AMICUS CURIAE*

The American Academy of Pediatrics (the "Academy") is a national non-profit medical specialty society of more than 45,000 board-certified pediatricians. Its principal purpose is to promote the attainment by all children of their full potential for physical, mental and social health. To that end, the Academy advocates for children and their right to medical care through various means, including the adoption of professional policies, educational programs, efforts to influence social and governmental policy and, occasionally, litigation.

The Academy participated prominently in the development of the National Childhood Vaccine Injury Act of 1986 (the "Act"), the interpretation and application of

which are at issue in this case. By significantly enlarging the number of persons entitled to compensation under the Act through including those injured by means other than vaccination, the decision below threatens childhood immunization in the United States, and as a consequence, children's health.

## SUMMARY OF ARGUMENT

Congress established a Vaccine Injury Compensation Program (the "Program") to create a compensation system that was not so burdensome to manufacturers as to be a disincentive for vaccine production and to compensate those few children injured by vaccines. The decision below misconstrues the eligibility requirements for compensation under the Program and, by extending the possibility of compensation to children injured by causes other than vaccines, undermines the purposes and threatens the fiscal integrity of the Program.

While expressing no opinion as to respondents' rights, the Academy urges the Court to reject both interpretations of the National Childhood Vaccine Injury Act announced by the court of appeals. The court erred in holding, first, that a presumption of eligibility for compensation can be established when manifestations of injury *preceded* vaccination and, second, that the government can overcome such a presumption only by proving the *cause*—not merely the existence of—the factor other than vaccination that caused the injury.

The first holding is inherently illogical. Given the state of medical knowledge, the second could not be satisfied in many instances where vaccines, in fact, played no role in a child's injury. Most significantly, neither the plain meaning of the Act nor its legislative history supports these interpretations.



## ARGUMENT

### I. THE NATIONAL CHILDHOOD VACCINE INJURY ACT COVERS ONLY INJURIES PRESUMED OR SHOWN TO HAVE BEEN CAUSED BY THE ADMINISTRATION OF VACCINE. THUS, THE COURT OF APPEALS ERRED IN HOLDING THAT A PRESUMPTION OF ELIGIBILITY FOR COMPENSATION CAN BE ESTABLISHED UNDER THE ACT WHEN INJURY PRECEDED VACCINATION.

In response to a public health crisis, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660), which was intended to address two pressing concerns; namely,

> (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market.[1]

The Act establishes the National Vaccine Injury Compensation Program, a method of compensating persons presumably injured by vaccines. Under the Act, a petitioner for compensation may establish causation in either of two ways. The first is to demonstrate that an injury or death meets criteria set out in the statute's "Vaccine Injury Table" (the "Table").[2] The Table, which is based on medical evidence, defines certain vaccine-related injuries and prescribes time limits following vaccination

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[1] H.R. Rep. No. 908, 99th Cong., 2d Sess. pt. 1, at 7 (1986) ("House Report"). On the floor, both Senator Kennedy (Congressional Record, October 18, 1986, at S17345) and Representative Waxman (Congressional Record, October 17, 1986, at H11589) noted that as a result of civil litigation over vaccine injuries a few plaintiffs received large awards while most received nothing, and that vaccine manufacturers' price increases to cover liability costs were threatening to leave the United States without sufficient access to vaccines.

[2] 42 U.S.C. § 300aa-14.

within which they must occur if compensation is to be awarded. Once a petitioner has proven that his or her injury fits within the Table, the burden shifts to the government to prove that a factor other than the vaccine caused the injury. A petitioner whose injury does not meet the Table criteria is entitled to no presumption and must use other means to establish causation.

The court below, relying primarily on a heading in the Table and ignoring the language of the Act itself, has greatly expanded the scope of the Act. The court's interpretation is supported neither by the Act's plain meaning nor legislative history, requires more certainty than is medically possible, and threatens the fiscal integrity of the compensation Program.

In reporting the Act (H.R. 5546) favorably to the House of Representatives, the Committee on Energy and Commerce stated that "The bill establishes a compensation system for those persons injured by routine pediatric vaccines" and that the Act was "intended to compensate persons with recognized vaccine injuries. . . ." [3] Referring to the type of injury at issue in this litigation, the Report stated that:

> if the cause of an encephalopathy is an infection or another condition not related to the vaccine, the encephalopathy is not to be considered compensable.[4]

Thus, it is clear that Congress intended to compensate *only injuries presumed to have been caused by the administration of vaccines.*

The Committee reported also that "a finding of causation is deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table." [5] For other injuries, a petitioner "must affirmatively demonstrate that the injury or aggravation was caused by the vaccine." [6]

[3] House Report at 12.

[4] House Report at 19.

[5] House Report at 15.



Contrary to Congress's intent, however, the court of appeals held that a child who displays symptoms of a Table injury within the specified time after vaccination establishes a presumption of causation even if the injury—and previous manifestations of it—occurred *before* vaccination. In so holding, the court relied on the fact that:

> Nowhere does the statute expressly state that proof of a Table encephalopathy includes a showing that the child sustained no injury prior to administration of the vaccine.[7]

Also, the court noted that "the Table language is that the first symptom *after vaccine administration* must occur within Table time, not, as the Secretary argues, the first of all manifestations must so occur." [8]

The court's interpretation, however, is at odds with the House Report in several respects. First, an injury that predates vaccination cannot be one of "those *injuries* listed in the Table *which occur* within the time period set forth in the Table." [9] (emphasis added) Such an injury has, by definition, already occurred. What is observable after vaccination is simply a *manifestation* of the injury. Second, the House Report's statement, quoted above, that causation is to be deemed to exist for Table injuries, in no way indicates that Congress was indifferent to causation or considered it irrelevant to compensation.[10] To the con-

[6] House Report at 15.

[7] *Whitecotton v. Secretary of Dep't of Health and Human Servs.*, 17 F.3d 374, 376 (Fed. Cir.), *cert. granted*, 115 S. Ct. 416 (1994).

[8] *Id.*

[9] See text at note 5.

[10] It is true that a few injuries that occurred before vaccination will doubtless be compensated under the Act. These are injuries that were not recognized before vaccination, but caused Table symptoms within the statutory period, and could not be shown by

trary, the evidence cited above of Congress' intention to compensate only for vaccine injuries, as well as other language from the House Report,[11] demonstrates Congress' wish that the presumption of eligibility not apply in cases of preexisting injuries. Finally, the House Report directly contradicts the court of appeals' interpretation by stating:

> The Vaccine Injury Table sets forth a list of vaccines, injuries, and time periods of *initial onset* of injuries. If a listed injury is *first made manifest* within the time period specified in the Table following the administration of the vaccine listed in the Table, the injury is to be considered compensable. . . .[12] (emphasis added)

Legislative history aside, the text of the statute requires a different result than that reached by the court below. The court of appeals identified two sections of the Act as specifying the time within which Table injuries must occur in relationship to vaccination, and based its holding on its construction of these provisions. In the first reference, an event is described as compensable if:

> the first symptom or manifestation of the onset or of the significant aggravation of any such illness, dis-

a preponderance of evidence to result from another identifiable factor, illness, or condition. Congress understood and accepted the fact that some overcompensation would occur. See note 11 *infra*. However, such overcompensation is simply the unavoidable cost of operating the program in an environment where medical knowledge is less than perfect. Nowhere in the Act or its legislative history did Congress indicate a desire to compensate under the Program individuals who were not actually injured by vaccines.

[11] In defending the presumption as to Table injuries, the Committee recognized the existence of "public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination" and suggested that revisions to the Table should be entertained when more information on vaccine effects became available. The House Report stated that the Act "does not include compensation for conditions which might legitimately be described as preexisting". House Report at 15.

[12] House Report at 19.



> ability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table. . . .[13]

The plain meaning of this provision, as the court of appeals recognized,[14] is that the symptom or manifestation must have occurred *for the first time* following vaccination. Under this language, an injury that was manifest before vaccination would not qualify for compensation.

The other reference or references[15] cited by the court of appeals are located in the Table section of the Act, 42 U.S.C. § 300aa-14(a). One of the two references in that section appears in the paragraph introducing the Table and the other, which is nearly identical and on which the court relied,[16] is simply the heading above a column of time periods. The heading reads:

> Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:[17]

The court of appeals construed this heading as meaning that events preceding vaccination are irrelevant. That is, a listed symptom occurring within the specified time *after* vaccination satisfies the Table, no matter how often the same symptom occurred before vaccination. Having concluded that the provisions of the two sections conflict, the court elected to honor the Table section, for no stated reason other than that Congress could have "expressly

[13] 42 U.S.C. § 300aa-11(c)(1)(C)(i).

[14] *Supra* note 7, at 376.

[15] The court of appeals cited the Table section for its interpretation, without stating that the section contains two iterations of the time requirement. *Whitecotton v. Secretary of Dep't of Health and Human Servs.*, 17 F.3d 374 at 376.

[16] *Id.*

[17] 42 U.S.C. § 300aa-14(a).

made the absence of preexisting injury an element of the prima facie case had it so intended." [18]

In fact, however, the provisions on time of occurrence in the two sections of the statute construed by the court of appeals [19] do not conflict, if one recognizes that what has already been stated completely in the text of a statute need not be fully repeated in a table.[20] The Table heading that the court of appeals quotes is a summary or shorthand for the complete statement found in the text of the Act at 42 U.S.C. § 300aa-11(c)(1)(C)(i), which precedes the Table section. The Table heading should be read as a reference to the earlier provision, rather than as a restatement in full or, as the court of appeals maintained, an alteration of the text's meaning *significantly* by omission of a portion of the text requirement. Further support for this interpretation lies in the general rule of statutory construction that provisions within the body of a statute are to be read together and an effort must be made to harmonize provisions with one another and with the purpose of a statute.[21]

In addition to the references discussed above, a third section of the Act refers to the time in which injury occurs. This section of the Act, which the court of appeals ignored in its decision, reads in relevant part:

> The . . . court may find the *first symptom* or manifestation of onset . . . occurred within the time period described in the Vaccine Injury Table even though

[18] *Supra* note 7, at 376.

[19] 42 U.S.C. § 300aa-11(c)(1)(C)(i) and 42 U.S.C. § 300aa-14(a).

[20] Usually, a table summarizes information available elsewhere. The word is defined as "a systematic arrangement of data usually in rows and columns for ready reference" and "a condensed enumeration". *Webster's Ninth New Collegiate Dictionary.*

[21] Norman J. Singer, *Sutherland Stat. Const.* (5th ed.) § 47.06. *Purview provisions*, citing *Murphy v. Nilsen*, 19 Or. App. 292, 527 P.2d 736 (1974). See also § 46.05. *"Whole statute" interpretation*, quoting *Sturges v. Crowninshield*, 17 U.S. 122, 202 (1819).



> the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.[22] (emphasis added)

This third section's reference, which also precedes the Table section, bolsters the Academy's and the government's argument. Why should it be expected that the Act, having stated twice already in text that the first symptom or manifestation of a compensable injury must occur after vaccination, would repeat that statement at full length in the Table heading?

## II. THE COURT OF APPEALS ERRED IN HOLDING THAT THE GOVERNMENT MUST PROVE, NOT MERELY THAT A FACTOR OTHER THAN VACCINATION CAUSED THE INJURY, BUT ALSO THE PRECISE CAUSE OF THE CAUSATIVE FACTOR.

The court of appeals' second holding addresses the government's ability to overcome the presumption of eligibility established by a petitioner who meets the Table requirements. The court would allow the government to defeat the presumption only if the Secretary can prove the specific cause—not merely the existence of—a preexisting condition that is shown by a preponderance of the evidence to have caused the injury. Again, the plain meaning of the statute does not support this holding. Moreover, a later decision of the same court appears to reject it.

Once a petitioner has met his or her initial burden, Congress specified that the government have an opportunity to demonstrate that injury resulted from other factors. The Act provides that compensation is due if petitioner meets his burden and the government fails to prove by

> a preponderance of the evidence that the illness, disability, injury, condition, or death described in the

[22] 42 U.S.C. § 300aa-13(b)(2).

> petition is due to factors unrelated to the administration of the vaccine. . . .[23]

Next, the Act limits what evidence the government may use, as follows:

> the term "factors unrelated to the administration of the vaccine"—(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition. . . .[24]

In short, the government must prove that the petitioner's injury emanated from a source other than the vaccine, not simply speculate as to that possibility. The government thus may not disclaim knowledge of what caused a child's symptoms after vaccination and thereby deny compensation.

The Act provides, however, that if the government *can* prove that another factor caused the injury, the petitioner's request for compensation must be denied. The Act contains no requirement that the Secretary also prove what caused the other factor. As is explained below, and as Congress surely knew, the cause or causes of many conditions affecting children before and soon after birth are not fully comprehended, though the conditions are known to occur and are readily recognized.

In September, 1994, another panel[25] of the Court of Appeals for the Federal Circuit reached a different decision on this point than that in the case under review. In *Knudsen v. Secretary of Dep't of Health and Human Servs.*, (*Knudsen*)[26], the court held that the government

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[23] 42 U.S.C. § 300aa-13(a)(1)(B).

[24] 42 U.S.C. § 300aa-13(a)(2)(A).

[25] *Whitecotton v. Secretary of Dep't of Health and Human Servs.* was decided by Judges Newman and Mayer; *Knudsen*, by Chief Judge Archer and Judge Nies. Judge Clevenger was a member of both panels.

[26] 35 F.3d 543 (Fed. Cir. 1994).



could defeat a compensation claim by offering proof of an alternative cause of injury—there, a viral infection—although the cause of the infection was unknown. In the court's words:

> there is nothing in the Vaccine Act that requires a *per se* rule that alternative causation cannot be proved when the specific virus is not identified. Accordingly, we hold that a "viral infection" *can* be an alternative causation, even though the viral infection is not in the particular case specifically identified by type or name.[27]

*Knudsen*'s holding on this point is correct, because it allows the government to prevail if it proves that the vaccination at issue did not cause the claimant's injury. Requiring more, as the court below has done in this case, goes far beyond what is necessary to disprove the vaccine's connection to the injury.

## III. THE COURT OF APPEALS' SECOND HOLDING IS MEDICALLY UNWORKABLE.

The court of appeals' second holding, that only preexisting conditions with known causes can overcome a petitioner's presumption of eligibility, would have serious implications for the nation's vaccine program. Unfortunately, so little is known of the causes of prenatal and perinatal injuries that under the court of appeals' holding a presumption once established would be inordinately difficult to defeat.

Medical literature is replete with acknowledgments of ignorance and uncertainties by eminent researchers as to the causation of birth defects and perinatal injury and illness. The examples immediately following are selected from a compilation of major studies published by the National Institutes of Health. Together, these statements demonstrate that the government frequently could not

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[27] *Id.* at 549.

satisfy the court of appeals' order to show the cause of the "factor unrelated" to the vaccine that is responsible for a child's injuries.

> The infectious diseases of major importance to the developing nervous system are rubella, cytomegalovirus, herpes simplex and toxoplasmosis. In addition, there is circumstantial evidence that in a significant number of instances the developing nervous system is damaged by unidentified infectious agents.[28]
>
> Approximately 3 percent of children have major malformations . . . present at birth. . . . The cause of most malformations is unknown, and only a limited number of drugs, chemicals or toxins have been positively implicated.[29]
>
> [F]or 30-40 percent of developmental defects, knowledge about cause is altogether lacking.[30]
>
> The first question parents of a child with neurologic damage ask their physician is 'What caused the damage?' . . . Even when we know that one event, such as asphyxia, *can* cause neurologic damage, we cannot be certain in most cases that the asphyxia *did* cause such damage.
>
> Physicians usually establish cause of disease by eliminating candidates from the classic disease categories —genetic, metabolic, traumatic, tumor, degenerative, vascular or infectious. But, in infants and children with CP [cerebral palsy] and MR [mental retardation], this method often fails to provide definite evidence of cause.[31]

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[28] Hugo W. Moser, "Biologic Factors of Development", *Prenatal and Perinatal Factors Associated with Brain Disorders* at 146 (John M. Freeman, ed., U.S. Dep't of Health and Human Services, NIH Publication No. 85-1149, April 1985) (*"Prenatal and Perinatal Factors"*).

[29] *Id.* at 142.

[30] *Id.* at 121.

[31] John M. Freeman, "Introduction", *Prenatal and Perinatal Factors* at 2.



> In spite of the many known causes of mental retardation, the exact defect in the majority of individual patients is unknown. . . .[32] The large group of retarded resulting from prenatal causes may be separated into three major divisions: cases due to genetic factors, those due to external factors that impair fetal development, and a large remaining portion of cases of clearly prenatal but otherwise unknown etiology.[33]

An article on congenital defects acknowledges that

> During pregnancy maternal, fetal, and environmental factors may cause microcephaly. Many cases of microcephaly are sporadic and no underlying cause is identifiable. Pathologic conditions that retard brain growth after birth and during the first year or two of life also may lead to microcephaly.[34]

Medicine's present inability to resolve the causation of most early childhood injury of various kinds is even more pronounced than the foregoing suggests. Often, when a cause *can* be identified for a particular child's condition, it is simply a name for a sequence of events that remains mysterious. It is not known, for example, why chromosomal transmutations occur in embryos or by what mechanism they frequently produce mental retardation. A case in point is Down syndrome, a single type of chromosomal abnormality, which accounts for one in three cases of severe mental retardation[35]. With a Down syndrome child, it is possible to know with reasonable certainty that the syndrome (three #21 chromosomes instead of two)

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[32] Harrie R. Chamberlin, "Mental Retardation", *Pediatric Neurology* at 154 (Thomas D. Farmer, ed., Harper & Row, Phila. 1983) (3d ed.)

[33] *Id.* at 155.

[34] Ronald I. Jacobson, "Congenital Structural Defects", *Pediatric Neurology: Principles and Practice* (Kenneth F. Swaiman, ed., The C.V. Mosby Co., St. Louis 1989).

[35] Moser, *supra* note 28, *Prenatal and Perinatal Factors* at 122.

caused a particular injury—for example, respiratory distress. However, it is not known at present what caused the trisomy to occur.

Finally, even in the rare instance where an event frequently associated with neurologic damage is known to have taken place,[36] it cannot be predicted with any degree of certainty that the child in question was injured and will, at some point, exhibit brain damage.[37] The event may have befallen a child stronger or weaker than most [38] and, too, subsequent events may worsen or ameliorate the effects of the original occurrence.[39]

These layers of scientific uncertainty as to causation and effect of perinatal injury render the court of appeals' newly imposed requirement unworkable. Even if the presence of an injury or condition were abundantly clear before vaccination, the government could not, in many instances, establish the cause of the condition. In these cases, the petitioner could recover under the Act even where all parties agreed that the injury was not caused by a vaccine.

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[36] As to birth injuries, "[d]ocumenting damage within the brain at the time it occurs remains a problem. There is limited ability to record what is actually taking place in the brain. . . . Instead, fetal distress is studied indirectly wtih systemic, biophysical, and biochemical techniques." Mortimer G. Rosen, "Factors During Labor and Delivery That Influence Brain Disorders", *Prenatal and Perinatal Factors* at 244.

[37] Task Force on Joint Assessment of Prenatal and Perinatal Factors Associated with Brain Disorders, "National Institutes of Health Report on Causes of Mental Retardation and Cerebral Palsy", 76 *Pediatrics* 457-58, No. 3 (Sept. 1985) (*"NIH Report"*). For a study of this phenomenon with respect to one type of injury and one possible effect thereof, see John M. Freeman & Karin B. Nelson, "Intrapartum Asphyxia and Cerebral Palsy", 82 *Pediatrics* 240-49, No. 2 (Aug. 1988).

[38] *NIH Report* at 458.

[39] Gordon Avery, "Effects of Social, Cultural and Economic Factors on Brain Development", *Prenatal and Perinatal Factors* at 613.



## IV. AFFIRMANCE OF THE COURT OF APPEALS' DECISION MAY DISCOURAGE APPROPRIATE VACCINATION OF CHILDREN.

If the court of appeals' erroneous decision is upheld, there may be unintended consequences that could threaten the well being of children. Two bodies presently serve as the primary authorities for advising physicians in the United States on the administration of vaccines to children: the Advisory Committee on Immunization Practices of the United States Public Health Service and the Committee on Infectious Diseases of the American Academy of Pediatrics. In recent years both bodies have issued stronger, more explicit recommendations on the need to immunize children with recognized or suspected neurologic handicaps of known and unknown causation.[40] These stronger recommendations are based on recent scientific information regarding the safety of vaccines,[41] on the entitlement of such children to receive immunization, and on their enhanced risk of exposure to, and complications from, vaccine-preventable diseases.

If the court of appeals' decision remains in effect, these committees may conclude that they are obligated to inform physicians that immunizing children with preexisting conditions can result in liability for the vaccine compensation program, vaccine manufacturers, or the adminis-

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[40] Centers for Disease Control and Prevention, "Diptheria, tetanus and pertussis: recommendations for vaccine use and other preventive measures": *Recommendations of the Immunization Practicues Advisory Committee (ACIP)*, MMWR 1991:40 (No. RR-10) 1-28; *Report of the Committee on Infectious Diseases* 365-67 (American Academy of Pediatrics, Peter G. Peter, ed., Elk Grove Village, Ill.) (23d ed. 1994).

[41] Kathleen R. Stratton, et al., *Adverse Events Associated with Childhood Vaccines* (Institute of Medicine, National Academy Press, Wash. D.C. 1994); Christopher P. Howson, et al., *Adverse Effects of Pertussis and Rubella Vaccines* (Institute of Medicine, National Academy Press, Wash., D.C. 1991).

tering physician.[42] The Academy would, of course, urge physicians to act only on the basis of medical indications for immunization, and presumably most physicians would do so. Still, it would be unreasonable not to expect some influence on physicians' willingness to immunize children with underlying neurologic disorders. Any decrease in immunization would be highly regrettable, because, as noted, children with neurologic impairments are more than usually susceptible to complications of diseases for which vaccination is available.

## V. EXPANSION OF THE GROUP ELIGIBLE FOR COMPENSATION UNDER THE ACT THREATENS THE FISCAL INTEGRITY OF THE PROGRAM.

The compensation program established by the National Childhood Vaccine Injury Act of 1986 derives its funding primarily from two sources: for so-called "preenactment" cases (claims associated with the administration of a vaccine prior to the effective date of the compensation law)[43] awards are paid from sums appropriated annually to the Department of Health and Human Services, with a current limitation of $110,000,000 per fiscal year.[44] Claims associated with the administration of a vaccine on or after the law's effective date (so-called "post-enactment" cases), are paid from the Vaccine Injury Compensation Trust Fund.[45] A tax, or surcharge, is imposed on each dose of the various childhood vaccines to keep the Fund

[42] Anyone claiming damages greater than $1000 associated with a vaccine administered after October 1, 1988 must first petition the Federal Court of Claims for compensation, 42 U.S.C. § 300aa-11 (a) (2) (A). After the court has ruled, however, civil actions may be initiated, 42 U.S.C. § 300aa-21 (a).

[43] The effective date is October 1, 1988.

[44] 42 U.S.C. § 300aa-15 (j).

[45] 26 U.S.C. § 9510. The Fund was established by P.L. 100-203, enacted a year after the enactment of the law establishing the National Vaccine Injury Compensation Program.



solvent.[46] Amounts equivalent to the net revenues received in the Treasury as a result of the vaccine surcharge are automatically paid into the Fund.[47]

The per-dose taxes [48] were established by Congress after hearings during which expert testimony was received, estimating necessary individual surcharges based in part on numbers of cases eligible for compensation. *See*, generally *Funding of the Childhood Vaccine Program: Hearing Before the Subcommittee on Select Revenue Measures of the House Committee on Ways and Means*, 100th Cong., 1st Sess. (1987) (Statement of John C. Butler III, Principal, Putnam Hayes & Bartlett, Inc.). Per-dose cost estimates received during the hearing were based primarily upon data on the reported incidence of various types of adverse reactions to vaccines paid for by the public sector; these data were collected by the Centers for Disease Control and Prevention. *Id.*

The Academy shares the government's belief that major expansion of eligibility for compensation would threaten, and could destroy, the compensation program.[49] Because of fiscal caps on funding mechanisms that support both "pre-enactment" and "post-enactment" awards, permitting compensation of other injuries would destroy the economic premise for both the appropriations limitation and the tax and, thus, the program's funding.

[46] 26 U.S.C. § 4131.

[47] 26 U.S.C. § 9510.

[48] The amount of tax imposed is as follows: DPT vaccine—$4.56; DT Vaccine—$0.06; MMR vaccine—$4.44; Polio Vaccine—$0.29.

[49] No. 94-372, *Secretary of Dep't of Health and Human Servs. v. Whitecotton*, Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit 19-21, asserting that the decision below "could readily require more than $200 million in additional compensation over the next ten years." *Id.* at 20.

In addition, under the Act [50] so-called post-enactment cases must initially be filed with the Federal Court of Claims; no such limitation applies to pre-enactment cases and the claimant may choose between civil litigation and the federal no-fault approach. For fiscal reasons, Congress established a limit of 3500 pre-enactment cases.[51] Thereafter, the no-fault alternative is no longer available to persons injured before passage of the Act. Thus, to expand the compensation system beyond persons presumed to have been injured as a result of administration of a covered vaccine could have the effect of returning many pre-enactment cases to the tort system defeating the principal purpose of the vaccine compensation law.

## CONCLUSION

The decision of the Court of Appeals for the Federal Circuit should be reversed insofar as it allows recovery for injuries unrelated to vaccination and prevents proof of causation by another factor unless the cause of the factor is known. *Amicus curiae* takes no position on respondents' entitlement to compensation.

Respectfully submitted,

STEPHAN E. LAWTON *
ANNE M. DELLINGER
HOGAN & HARTSON
555 13th Street, N.W.
Washington, D.C. 20004
(202) 637-5600
*Attorneys for the Amicus Curiae*
* Counsel of Record

December 15, 1994

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[50] 42 U.S.C. § 300aa-11(a)(2)(A).

[51] 42 U.S.C. § 300aa-11(b)(1)(B).

(9)

No. 94-572

IN THE
# Supreme Court of the United States
OCTOBER TERM, 1994

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DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,
*Petitioner,*

v.

MARGARET WHITECOTTON, *et al.*,
*Respondents.*

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**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

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## DISSATISFIED PARENTS TOGETHER, UNITED CEREBRAL PALSY ASSOCIATION, NATIONAL TUBEROUS SCLEROSIS ASSOCIATION, AND CENTER ON DISABILITY AND HEALTH, AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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CURTIS R. WEBB
155 Second Avenue North
P.O. Box 1768
Twin Falls, ID 83301
(208) 734-1616
*Attorney for the Amici Curiae*

January 17, 1995

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IN THE

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OCTOBER TERM, 1994

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No. 94-372

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DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,
*Petitioner*,

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*Respondents.*

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**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

---

**DISSATISFIED PARENTS TOGETHER, UNITED CEREBRAL PALSY ASSOCIATION, NATIONAL TUBEROUS SCLEROSIS ASSOCIATION, AND CENTER ON DISABILITY AND HEALTH, AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS**

---

## INTEREST OF *AMICI CURIAE*

Dissatisfied Parents Together is a non-profit nationwide organization of parents concerned about vaccine safety. Many of our members are the parents of individuals who have been injured or killed by vaccines.

Dissatisfied Parents Together participated prominently in the development of the National Childhood Vaccine Injury Act, and has remained deeply involved in the implementation of the National Vaccine Injury Compensation Program created by the Act.

United Cerebral Palsy Association is a confederation representing 152 state and local affiliates providing services to and advocating on behalf of 500,000 children and adults with cerebral palsy and their families. As part of our mission to improve the quality of life for persons with cerebral palsy, and others with severe disabilities, we promote personal health, home and public safety; influence the passage of laws and the allocation of public and private resources; and advocate for the development of family support systems that can nurture and provide for the needs of all family members including the family member with a disability.

The National Tuberous Sclerosis Associa ion is a non-profit organization that provides support and advocacy for individuals with tuberous sclerosis and their families. Although tuberous sclerosis is present from birth, children with tuberous sclerosis are developmentally normal unless they develop seizures. Some children with tuberous sclerosis have their first seizures within a few days of a vaccination. The decision of the court of appeals correctly affords the statutory presumption to such children.

The Center on Disability and Health is a non-profit organization which serves as a resource to the disability community for conducting research, providing technical assistance, developing educational materials, and promoting health care reform from a disability prospective.

We believe that the court of appeals correctly decided the issue of when a child is entitled to the presumption of entitlement. We believe the standards for which the Secretary of Health and Human Services argues would defeat this central feature of the Program and deny compensation to many vaccine injured individuals.

## SUMMARY OF ARGUMENT

The National Childhood Vaccine Injury Act provides a presumption that an individual who satisfies the conditions of the Vaccine Injury Table will be compensated.



This presumption greatly simplifies the determination of entitlement to compensation, and thereby, creates the relative simplicity, certainty and generosity which Congress intended the compensation program it created to provide.

The court of appeal's decision correctly afforded the presumption to a young woman who was healthy and developmentally normal until six hours after her third DTP vaccination. As Amici Curiae in support of Respondents, we urge the Court to affirm.

We also urge the Court to affirm the court of appeal's decision that the presumption that an individual will be compensated cannot be defeated unless the Secretary of Health and Human Services can establish a specific, known, cause for the individual's illness.

## ARGUMENT

### I. THE NATIONAL CHILDHOOD VACCINE INJURY ACT PROVIDES A PRESUMPTION THAT AN INDIVIDUAL WHO SATISFIES THE CONDITIONS OF THE VACCINE INJURY TABLE WILL BE COMPENSATED UNLESS THE SECRETARY ESTABLISHES A KNOWN CAUSE FOR THE INDIVIDUAL'S CONDITION WHICH IS UNRELATED TO THE VACCINATION.

The statute establishes a presumption that an individual who satisfies the conditions of the Vaccine Injury Table should be compensated. Although many decisions refer to this presumption as a "presumption of causation", it is actually more.

The statute provides that an individual who demonstrates the matters required by 42 U.S.C. Sec. 300aa-11(c) "shall be compensated" unless it is proven that her condition "is due to factors unrelated to the administration of the vaccine." 42 U.S.C. Sec. 300aa-13(a)(1). In most cases the critical matter required by 42 U.S.C. Sec. 300aa-11(c) is satisfaction of the conditions of the

Vaccine Injury Table. Once this is established, this is presumed that the person will be compensated.

This is a legal presumption and cannot be defeated by evidence that the vaccine could not have caused the individual's condition. The only way to defeat the presumption is for the Secretary of Health and Human Services to establish that a known cause, unrelated to the vaccination, caused the individual's condition. The statute carefully limits this defense to known causes.

> "For purposes of paragraph (42 U.S.C. 300aa-13 (a)(1)). The term "factors unrelated to the administration of the vaccine"—
>
> (A) Does not include any idiopathic, unexplained, unknown, hypothetical or undocumentable cause, factor, injury, illness, or condition and
>
> (B) May, as documented by the Petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and perinatal anoxia) or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case have shown to have been the agent or agents principally responsible for causing the Petitioner's illness, disability, injury, condition, or death.

42 U.S.C. Sec. 300aa-13(a)(2).

This presumption is a key feature of the National Vaccine Injury Compensation Program. The legislative history of the Act makes no secret of the breadth of the presumption.

> "The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related."
>
> . . . . .
>
> "The Vaccine Injury Table sets forth a list of vaccines, injuries, and time periods of initial onset of injuries. *If a listed injury is first made manifest within the time period specified in the Table following the administration of the vaccine listed in the Table, the injury is to be considered compensable* (unless there is other evidence to the contrary, as described above in Section 2113)."

H.R. Rep. 908, 99th Cong., 2d Sess., pt. 1 at 18-19, *reprinted in* U.S. Code Cong. and Admin. News 6344, 6359-6360 (Emphasis added).

The two overriding concerns which led to the enactment of the National Childhood Injury Act were: 1) the inadequacy of the tort system (uncertainty and expense for both injured individuals and vaccine manufacturers), and; 2) the instability and unpredictability of the childhood vaccine market (as a result of unpredictable liability expense). *Id.* at 7, *reprinted in* U.S. Code Cong. and Admin. News 6344, 6348. A broad presumption of compensability was essential to both these purposes.

> "The Committee anticipates that the speed of the compensation program, the low transaction cost of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the systems awards will divert a significant number of potential plaintiffs from litigation."

*Id.* at p. 13, *reprited in* U.S. Code Cong. and Admin. News 6344, 6354.

The National Vaccine Injury Compensation Program offers a non-exclusive remedy. It shields vaccine manufacturers from liability, and thereby encourages stability and predictability to the childhood vaccine market by attracting injured individuals into the Program and by encouraging them to accept the compensation awarded

through the Program. Congress recognized that this could be accomplished only through a broad presumption that individuals who satisfied the conditions of the Vaccine Injury Table would be compensated.

## II. AN INDIVIDUAL WHO ESTABLISHES THAT THE FIRST SYMPTOM OR MANIFESTATION OF ONSET OR SIGNIFICANT AGGRAVATION OF A CONDITION SET FORTH IN THE VACCINE INJURY TABLE WITHIN THE PERIOD SPECIFIED IN THE VACCINE INJURY TABLE BENEFITS FROM THE PRESUMPTION THAT SHE WILL BE COMPENSATED.

The central controversy before the Court is over what an individual must establish in order to benefit from the statutory presumption.

We have set out what we believe to be the correct analysis below. We have described the analysis separately for cases in which the presumption is premised upon the "onset" of a Table condition, and those in which the presumption is premised upon the "significant aggravation" of a Table condition.

Although the court of appeals decision addresses only the issue of "onset", the special master's decision is based upon errors in analyzing the conditions which establish the presumption in both "onset" and "aggravation" cases.

### A. An Individual Does Not Suffer the First Symptom or Manifestation of an Encephalopathy Until She Suffers a Symptom or Manifestation of Impairment of the *Function* of the Brain.

The statute clearly defines what an individual alleging the onset of a Table condition in association with a vaccination must prove to benefit from the statutory presumption that she is entitled to compensation.



#### 1. *What must be established.*

An individual is entitled to the presumption if she demonstrates by a preponderance of the evidence that she:

> "Sustained . . . an illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine . . . and the first symptom or manifestation of the onset . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table."

42 U.S.C. Sec. 300aa-11(c)(1)(C).

The two elements which the individual must establish are:

1. She suffers from a table condition; and

2. The first symptom or manifestation of the table condition occurred within the post-vaccination period provided in the Vaccine Injury Table.

The conditions covered in the Vaccine Injury Table are defined in the "Qualifications and Aids to Interpretation" section of the Vaccine Injury Table. 42 U.S.C. Sec. 300aa-14(b). The definitions in this section are critical because *only* "the first symptom or manifestation of onset" of an *Table* condition within the specified period provides the individual with the presumption.

In a case premised upon a Table encephalopathy, an individual must demonstrate the onset of a "significant . . . impairment of function of the brain" within the time period specified by the Vaccine Injury Table. 42 U.S.C. 300aa-14(b)(3)(A).

#### 2. *Legal standard applied.*

The facts of this case provide a good example of how the courts below should have applied the simple criteria in the statute.

Maggie Whitecotton was microcephalic, her head circumference was between the second and third percentile,

prior to her August 18, 1975 DTP vaccination. Maggie Whitecotton was healthy, developmentally and physically, until she received her August 18, 1975 DTP vaccination. Within six hours of receiving her August 18, 1975 DTP vaccination, Maggie Whitecotton suffered a series of seizures, within thirty-six hours she suffered a second series of seizures. The seizures Maggie Whitecotton suffered within thirty-six hours of her DTP vaccination were symptoms of an impairment of the function of her brain, an encephalopathy. Maggie Whitecotton's disabilities are sequelae of that encephalopathy.

Maggie Whitecotton's claim under the National Vaccine Injury Compensation Program is based upon the occurrence of a Table encephalopathy in association with her August 18, 1975 DTP vaccination. DTP vaccine is covered by the Vaccine Injury Table. An encephalopathy within three days of a DTP vaccination is "an illness, disability, injury, or condition" covered by the Vaccine Injury Table. 42 U.S.C. Sec. 300aa-14(a).

The covered condition "encephalopathy" is defined in the "Qualifications and Aid to Interpretation".

> "(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of *function of the brain*. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent and unusual screaming, persistent inconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.
>
> (B) If in a proceeding on a petition it is shown by a preponderance of evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 2111 of this title for vaccine-related injury or death it is not possible to determine the cause, by a preponderance of evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record."

42 U.S.C. Sec. 300aa-14(b)(3) (Emphasis added).



Maggie Whitecotton was clearly entitled to the presumption.

She suffers from a Table encephalopathy. All parties agree that Maggie Whitecotton suffered seizures, and suffers mental and physical disabilities which are symptoms of a "significant acquired abnormality of, or injury to, or impairment of function of the brain". See 42 U.S.C. Sec. 300aa-14(b)(3)(A).

Maggie Whitecotton's microcephaly had caused no impairment in the function of her brain, no observable problem in her health or development before her August 18 1975 DTP vaccination. The first symptoms of any "impairment of function of the brain", and therefore the Table encephalopathy were the seizures Maggie Whitecotton suffered within three days of her August 18, 1975 DTP vaccination.

The *only* encephalopathy relevant to the determination of Maggie Whitecotton's claim for compensation under the National Vaccine Injury Compensation Program is her "Table" encephalopathy. The occurrence of symptoms which do not satisfy the statute's definition of an encephalopathy prior to the vaccination does not effect her claim.

### 3. *Analysis of the decisions below.*

The special master's conclusion that microcephaly was the first symptom or manifestation of Maggie Whitecotton's Table encephalopathy is clearly wrong as a matter of law. A condition is a Table encephalopathy only if it impairs the "function of the brain", and microcephaly is not a measure of brain function. The court of appeals decision corrected this error, and should be affirmed.

## B. An Individual Suffers A Significant Aggravation of a Vaccine Injury Table Condition if a Comparison of the Symptoms of the Condition Before the Vaccination and the Symptoms Which Occur Within the Time Period Provided in the Vaccine Injury Table Demonstrates a Marked Change for the Worse.

The statute also defines what an individual alleging the significant aggravation of a Table condition in association with a vaccination must prove to benefit from the statutory presumption that she is entitled to compensation.

### 1. *What must be established.*

An individual is entitled to the presumption if she demonstrates by a preponderance of the evidence that she:

> ". . . had significantly aggravated an illness, disability, or condition set forth in the Vaccine Injury Table in association with the vaccine . . . and the first symptom or manifestation of . . . the significant aggravation . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table."

42 U.S.C. Sec. 300aa-11(c)(1)(C).

The statute defines "significant aggravation":

> "The term "significant aggravation" means any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health."



42 U.S.C. Sec. 300aa-33(d).

The two elements which the individual must establish are:

1. She suffered from a Table condition prior to the vaccination; and

2. There was a change for the worse in the Table condition in the post-vaccination period provided in the Vaccine Injury Table.

The change must result in "markedly greater disability, pain, or illness acompanied by substantial deterioration of health". 42 U.S.C. Sec. 300aa-33(d). This phrase is a measure of the significance of the change. It calls for a comparison of the observable symptoms before the vaccination and the observable symptoms within the time period after the vaccination prescribed by the Vaccine Injury Table.

The definition of "significant aggravation" does not require the individual to prove that the symptoms which occurred in the Table time period caused "markedly greater disability, pain, or illness" or that the changes observed in the Table time period would not have occured had she not been vaccinated. Requiring such proof would be equivalent to requiring proof of causation in fact—precisely the proof the presumption is intended to make unnecessary.

### 2. *Application of legal standard.*

The legislative history provides an example of how the simple criteria of the statute should be applied.

> "Significant aggravation" is defined below in Section 2133. The Committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in

> the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g. a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intended that the time periods set forth in the Table apply to the significant aggravation in order for causation to be deemed to exist (e.g., a significant deterioration of a seizure disorder after DTP vaccination must first become manifest within three days of the vaccination).

H.R. Rep. 908, 99th Cong., 2d Sess., pt. 1, at 15-16, *reprinted in* U.S. Code Cong. and Admin. News, 6344, pp. 6356-6357.

***3. An analysis of the decisions below.***

The special master's significant aggravation analysis relied upon the Court of Federal Claims decision in *Misasi v. HHS*, 23 Cl.Ct. 322 (1991) The critical language in the *Misasi* reads:

> "To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess an individual's condition prior to the administration of the vaccine, i.e., evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered."

23 Cl.Ct. at 324.

The special master's decision focused upon elements 3 and 4 in the *Misasi* decision's analysis concluding:



> "Maggie was born with a brain defect, and there was nothing that occurred in temporal relationship to the DPT vaccination which indicates that it is more likely than not that the vaccine permanently aggravated her condition."

J. App. p. 42a. The special master's findings of fact demonstrate the same analysis:

> "5. No significant aggravation of Maggie's *brain* disorder was manifest within three days following the said administration of the DPT vaccine.
>
> "6. The DPT vaccine did not cause a significant aggravation of Maggie's *condition*.

J. App. p. 42a.

The special master's analysis was clearly wrong. His focus was on a comparison of what Maggie Whitecotton's condition would have been had she not been vaccinated, and whether the DPT vaccination *caused* a significant aggravation of Maggie's condition. This analysis denied Maggie Whitecotton the statutory presumption and required her to prove causation in fact.

Recent decisions have uniformly held that steps 3 and 4 of the *Misasi* analysis apply *only* after the Secretary has established that the change in the child's Table condition was caused by a known factor unrelated to the vaccination. *Reusser v. HHS*, 28 Fed. Cl. 516 (1993); *Schumacher v. HHS*, 26 Cl.Ct. 1033 (1992), *aff'd* 2 F.3d 1128 (Fed. Cir. 1993). The special master erroneously applied steps 3 and 4 of the analysis without reaching the "factors unrelated" defense.

Since it is usually impossible to predict the course of a neurologic disorder, the special master's application of the *Misasi* standard abrogated Congress's intent to provide a presumption in cases in which a child suffered a change for the worse in a pre-existing Table condition following a vaccination.

The court of appeals did not reach the issue of pre-existing condition because it correctly concluded that Maggie Whitecotton was entitled to the presumption of entitlement on the basis of the onset of her Table encephalopathy.

## III. A "FACTOR UNRELATED TO THE VACCINATION" CAN BE ESTABLISHED ONLY BY ESTABLISHING A KNOWN, IDENTIFIABLE CAUSE FOR THE INDIVIDUAL'S CONDITION.

The court of appeals was clearly correct in its ruling that microcephaly of unknown origin cannot provide the basis for a "factor unrelated" defense. This is clear from the statute, 42 U.S.C. Sec. 300aa-13(a)(2), and from the precedent in the court of appeals.

The statute could hardly be clearer:

> "Sec. 300aa-13. Determination of eligibility and compensation
>
> "(a) General rule. (1) Compensation shall be awarded under the Program to a Petitioner if the special master or court finds on the record as a whole—
>
> "(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1) [42 U.S.C.S. Sec. 300aa-11(c)(1)], and
>
> "(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.
>
> "The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.
>
> "(2) For purposes of paragraph (1), the term 'factors unrelated to the administration of the vaccine'—



> "(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
>
> "(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbance which have no known relation to the vaccine involved by which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition or death."

42 U.S.C. Sec. 300aa-13(a).

Congress employed three nearly identical terms, "idiopathic,", "Unexplained", and "unknown" to avoid any confusion about the statute's intent to preclude a defense on the basis of a condition for which the cause was not known.

The court of appeal's precedent is equally clear. In *Koston v. HHS*, 974 F.2d 157 (Fed. Cir. 1992), the court held that unless the cause of an illness is known, it cannot provide the basis for the "factor unrelated" defense.

> "Our task is purely on a statutory interpretation. Section 30011-13(a)(1)(B) of the Vaccine Act bars compensation if there is 'a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine.' Accepting that Jenna exhibits the symptoms of Rett Syndrome, the question boils down to whether Rett Syndrome is a factor unrelated to the DPT vaccine. Section 300aa-13(a)(2)(A) defines unrelated factors as not including 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.' Since the word 'or' is used with both the adjectives (idopathic, unexplained, unknown, *or* hypothetical) and the norms

> (cause, factor, injury, illness, *or* condition), it is apparent that an unrelated factor is not an idiopathic illness, an unexplained illness, or an unknown cause. As Koston says, 'The statute is plain enough. An 'idiopathic' condition, or a condition with an 'unknown cause', is not a 'factor unrelated to the administration of the vaccine.' "

974 F.2d at 160.

Rett Syndrome is also present from birth, 974 F.2d at 160, so the *Koston* ruling resolved the issues raised by the Secretary in this case.

The rule in *Koston* is an important part of the expedited compensation program established by the National Childhood Vaccine Injury Act. The *Koston* court noted:

> "By the plain words of the statute, we have an unknown cause and seizures occurring within three days, the period the Vaccine Injury Table sets for recovery. 42 U.S.C. Sec. 300aa-14. That is the end of our inquiry, although we are also satisfied that this interpretation is consonant with the purpose of the statutory scheme which envisions that awards be made 'quickly, easily, and with certainty and generosity,' H.R. Rep. No. 908, 99th Cong., 2d Sess. 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6344, even if this results in compensation to some children whose illness is not, in fact, vaccine-related.' *Id.* at 18, 1986 U.S.C.C.A.N. at 6359. But even if we were to credit the Secretary's suggestion that Jenna's receipt of an unwarranted award would be an absurd result, we could only respond that we are interpreting the statute as Congress wrote it. Avoidance of absurdity, if such it be, is its responsibility, not ours. *Tennessee Valley Auth. v. Hill,* 437 U.S. 153, 194 (1978)."

974 F.2d at 161.

The court of appeals decision below is even clearer.

> "Congress intended that vaccine awards be made 'quickly, easily, and with certainty and generosity.'



> H.R. Rep. No. 908, 99th Cong., 2d Sess. 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6344. This purpose would not be served by allowing the Secretary to avoid an award by offering 'speculative or hypothetical matter or explanations' of alternate causation; under the Act, a Table injury must be presumed vaccine-related unless demonstrated to arise from 'other' defined 'illnesses or factors.' *Id.* at 18, 1986 U.S.C.C.A. at 6359. This may result in 'compensation to some children whose illness is not, in fact, vaccine related,' *Koston,* 974 F.2d at 161 (citations omitted), but that is what Congress intended. As in *Koston,* 'we have an unknown cause and (symptoms) occurring within three days, the period the Vaccine Injury Table sets for recovery. That is the end of our inquiry. . .' *Id.* The Whitecottons established their prima facie case, and so get benefit of presumptive causation."

17 F.3d 374, at 378.

Contrary to the Secretary's arguments, this rule leads to precisely the results Congress intended: relative simplicity, certainty, and generosity.

The court of appeals most recent decision in the area, *Knudsen v. HHS,* 35 F.3d 543 (Fed. Cir. 1994) also follows *Koston.* The court of appeals held that proof that a viral infection caused an encephalopathy can provide the basis for a factor unrelated defense. The court of appeals remanded the claim (which had been denied by the special master below) with instructions that the special master determine if the Secretary had proven that the child's encephalopathy was, in fact, caused by viral infection. 35 F.3d at 548-551.

The Secretary's criticism of *Koston* is premised upon the fundamental misconception of law which permeates this appeal: The Secretary's belief that the statute provides a presumption of causation only. This misconception leads the Secretary to believe that evidence that the vaccine did not cause a Table injury should defeat the presumption.

As we have explained above, the presumption is broader: that a person satisfying the conditions of the Vaccine Injury Table will be compensated. This legal presumption can be defeated only by the means recognized in the statute: by establishing a known cause for the child's condition which is unrelated to the vaccination.

## IV. THE COURT OF APPEALS DECISION DOES NOT THREATEN THE FISCAL INTEGRITY OF THE PROGRAM.

The American Academy of Pediatrics, as *amicus curiae* in support of the Secretary, has argued that the court of appeals decision "threatens the fiscal integrity of" the National Vaccine Injury Compensation Program. That is nonsense. The decision does not "expand" the conditions under which an individual is entitled to compensation. It does not, therefore, impact the "fiscal integrity" of the Program.

The Program's current annual appropriation of $110,000,000 is sufficient for cases arising from vaccinations administered prior to October 1, 1988, and there is a large surplus available in the trust fund for cases arising after October 1, 1988. Proceedings of the Advisory Commission on Childhood Vaccines, September 28, 1994, pp. 52-53. A measure of the weakness of this argument is the fact that the Secretary raised it in her Petition for Certiorari, but does not include it in her brief.



## CONCLUSION

**One of the central principles of the National Vaccine Injury Act is the broad presumption that persons satisfying the conditions of the Vaccine Injury Table will be compensated. The court of appeals honored that principle, correctly holding that: a healthy, developmentally normal child who developed symptoms of a Table encephalopathy within the time period specified in the Vaccine Injury Table was entitled to the presumption; and that a condition for which no cause can be established could not defeat the presumption. You should affirm the court of appeals decision.**

**Respectfully submitted,**

**CURTIS R. WEBB**
**155 Second Avenue North**
**P.O. Box 1768**
**Twin Falls, ID 83301**
**(208) 734-1616**
***Attorney for the Amici Curiae***

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